No. 24-2278

United States Court of Appeals for the Federal Circuit

JAZZ PHARMACEUTICALS, INC., JAZZ PHARMACEUTICALS IRELAND LIMITED,

Plaintiffs-Appellees,

v.

AVADEL CNS PHARMACEUTICALS, LLC,

Defendant-Appellant.

Appeal from the U.S. District Court for the District of Delaware, No. 21-1594, Hon. Gregory B. Williams

APPELLANT AVADEL CNS PHARMACEUTICALS, LLC'S NONCONFIDENTIAL EMERGENCY MOTION FOR STAY PENDING APPEAL

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September 6, 2024

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number: 24-2278

Short Case Caption: *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*

Filing Party/Entity: Avadel CNS Pharmaceuticals, LLC, Defendant-Appellant

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: September 6, 2024 Signature: */s/ Gabriel K. Bell*
Name: Gabriel K. Bell

1. Represented Entities. Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Avadel CNS Pharmaceuticals, LLC

2. Real Party in Interest. Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

None.

3. Parent Corporations and Stockholders. Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

Avadel CNS Pharmaceuticals, LLC is wholly owned subsidiary of Avadel US Holdings, Inc., which is a wholly owned subsidiary of Avadel Pharmaceuticals plc. Avadel Pharmaceuticals plc is a publicly traded company with no parent corporation. Janus Henderson Group plc, a publicly traded company, owns more than 10% of Avadel Pharmaceuticals plc's stock.

4. **Legal Representatives.** List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

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* No longer with firm.

5. **Related Cases.** Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

Yes.

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). Please do not duplicate information. This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. **Organizational Victims and Bankruptcy Cases.** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

None/Not Applicable.

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Pursuant to Federal Circuit Rule 25.1(e)(1)(B), Defendant-Appellant provides the following description of the general nature of the material redacted in the nonconfidential version of its motion:

The material omitted on pages 6, 19 of this motion relates to confidential business information subject to a protective order.

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INTRODUCTION

Defendant-Appellant Avadel seeks a stay pending appeal because the district court's injunction prohibits Avadel from conducting clinical trials and seeking FDA approval for new treatment regimes. That activity is unequivocally protected by the Patent Act's safe harbor, which provides that it "shall not be an act of infringement" for activities "reasonably related to the *development* and *submission* of information" to the FDA. 35 U.S.C. § 271(e)(1) (emphasis added); *see Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005); *Edwards Lifesciences Corp. v. Meril Life Sci. Pvt. Ltd*., 96 F.4th 1347, 1351 (Fed. Cir. 2024). Absent a stay pending appeal, therefore, the injunction threatens core activities that Congress deliberately protected. Even worse, Avadel's direct competitor—Plaintiff-Appellee Jazz—expansively interprets the injunction to cover even more protected safe-harbor activity, and effectively threatens Avadel with contempt if Avadel does not acquiesce immediately. Avadel proposed to Jazz ways to avoid the impact of the injunction at least until the district court (which is already acting promptly) and this Court rule on the motions to stay, but Jazz did not agree. Therefore, Avadel files this Emergency Motion for a stay pending appeal and seeks a temporary stay pending resolution of the motion.[1]

[1] Parties' counsel conferred diligently but reached an impasse on this motion; Jazz is expected to oppose and respond. *See* Exs. D-E, H-K.

Every factor favors a stay. First, Avadel is highly likely to succeed on the merits of its appeal from the district court's injunction. This appeal concerns *only* the scope of the injunction, not the underlying merits of Jazz's infringement claims against Avadel.[2] As to the injunction, there can be no real doubt that it is unlawful because it prohibits Avadel from engaging in conduct that is lawful under the Patent Act's safe harbor: conducting future clinical trials and seeking FDA approval for a new indication for Avadel's Lumryz product for patients suffering from idiopathic hypersomnia (IH). *See* 35 U.S.C. § 271(e)(1). Avadel cannot infringe Jazz's patent rights when it allegedly uses Jazz's patented invention to "develop[] and submi[t]" information to the FDA. *Id.* Accordingly, the district court cannot issue an injunction to prohibit Avadel from undertaking that non-infringing conduct. The district court overlooked that basic problem, and its consideration of the injunction factors was misguided in other respects. Notably, although the district court correctly *denied* an injunction as to Avadel's already-approved use of Lumryz for another indication (narcolepsy) based on the FDA's public interest determination that Lumryz is clinically superior, it then precluded FDA from making that determination as to IH.

[2] The district court entered the injunction before receiving or considering the parties' post-trial motions. Avadel will challenge the merits of Jazz's infringement claims in its post-trial motions and, if necessary, in a later appeal.

Furthermore, Jazz has interpreted the injunction in a manner that yields clearly unlawful results. According to Jazz, Avadel must stop enrolling new patients in its ongoing clinical trial and cannot provide "open label extension" (i.e., allowing trial patients to remain on the treatment) as part of the trial. That is contrary to the safe harbor.

Second, Avadel will suffer irreparable harm absent a stay. Avadel wishes to seek FDA approval of Lumryz for IH patients, and it wishes to do so as soon as possible. It has already begun one clinical trial for IH patients and may need to undertake others in the course of seeking FDA approval. If the district court's injunction remains in place during this appeal, it will disrupt Avadel's effort to secure FDA approval and its opportunity to promptly market Lumryz for IH upon FDA approval. The research and reputational harms of that delay are irreparable.

Third, a stay cannot harm Jazz (much less irreparably). If Avadel is permitted to undertake its clinical trials and submit information to the FDA during this appeal, nothing will happen to Jazz. FDA approval will not occur before the conclusion of this appeal. A stay would merely allow Avadel to continue its statutorily permitted activities of gathering and submitting information about Lumryz to the FDA while this appeal is litigated. That conduct cannot harm Jazz.

Fourth, the public interest favors a stay. Clinical trials are a public good, and a stay merely permits Avadel's clinical trials to proceed while this appeal is litigated.

No public benefit flows from inhibiting those activities pending appeal. The public is best served by having Lumryz approved for IH as soon as possible.

Therefore, this Court should issue a stay pending appeal and should grant a temporary stay pending consideration of this Emergency Motion.

BACKGROUND

A. Factual and Procedural Background

This motion addresses the latest chapter in Jazz's long-running effort to quash the FDA's consideration of Lumryz, Avadel's revolutionary once-nightly treatment for narcolepsy. Jazz markets a drug, Xyrem, which relies on a decades-old formulation to treat narcolepsy. In 2020, Jazz introduced Xywav, a mixed-oxybate salt formulation for narcolepsy and later obtained approval for IH. *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, No. 20-md-2966, 2023 WL 3440399, at *8 (N.D. Cal. May 12, 2023). Until recently, Xyrem was the only available treatment for narcolepsy, and Jazz charged monopoly prices. In 2020, for example, Medicare Part D paid Jazz an average of over $138,000 per beneficiary for Xyrem prescriptions, for a total cost of over $287 million.[3] But Xyrem and Jazz's successor product, Xywav, have a flaw: they require twice-nightly dosing, forcing patients who suffer from narcolepsy—a sleep disorder—to wake during the night every night.

[3] *See* Centers for Medicare & Medicaid Services, Medicare Part D Drug Spending, https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-d-spending-by-drug.

Avadel developed a new, once-nightly formulation called Lumryz designed to allow those suffering from narcolepsy to get an uninterrupted night's sleep. Lumryz is a threat to Jazz, and Jazz has aggressively sought to prevent the FDA from approving Lumryz. For years, Jazz blocked the FDA from considering Lumryz for approval by improperly listing a *computer-system* patent in the FDA's Orange Book—which this Court rejected last year, clearing the way for FDA approval of Lumryz to treat narcolepsy. *Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, 60 F.4th 1373, 1376-77, 1382 (Fed. Cir. 2023). The FDA issued that approval shortly thereafter and found that Lumryz's single-dose formulation was clinically superior to Xyrem and Xywav for narcolepsy patients. Ex. A (Injunction Op.) at 17. Yet Jazz continues to resist the FDA's approval of Lumryz through a quixotic Administrative Procedure Act lawsuit. *See Jazz Pharms., Inc. v. Becerra*, No. 23-cv-01819 (D.D.C.).

Jazz also sued Avadel for patent infringement in the present matter in 2021. That proceeding recently culminated in a multi-day jury trial. Before trial, the parties stipulated that Lumryz infringes claim 24 of Jazz's U.S. Patent No. 11,147,782 ('782 patent). The jury rejected Avadel's challenges to the validity of that claim, while also rejecting Jazz's infringement claims under another patent. *See* D.I.579. And the jury awarded a modest amount for past infringement of the '782 patent, resulting in an award of just under $233,563. *Id.* at 11.

B. The District Court's Injunction

Thereafter, the district court stated it would consider Jazz's motion for a permanent injunction before receiving the parties' post-trial motions. D.I.585 at 2. Jazz sought a blanket injunction that would prohibit Avadel from marketing Lumryz to anyone "through and including the expiration date of the '782 patent, including any … extensions granted thereon." D.I.586 at 6. Although Jazz's proposed injunction included a carveout for "currently-ongoing clinical trials," the proposed injunction otherwise provided that "Avadel may not seek approval from the [FDA] for any indication that was not already part of Lumryz's approved product labeling as of March 4, 2024." *Id.* This meant that Avadel would not be able to seek FDA approval to market Lumryz to patients suffering from IH, another sleep condition for which Xywav is approved.

Avadel opposed on numerous grounds, including on the fundamental ground that, with respect to IH patients, Avadel *cannot* infringe, since it lacks FDA approval to market Lumryz to IH patients. Ex. C (Injunction Hrg. Tr.) at 66. Avadel explained that, until it obtains FDA approval, its use of Lumryz for IH patients falls within the statutory safe harbor permitting conduct that would otherwise infringe if that conduct is intended to generate data for submission to FDA. *Id*. Thus, Avadel explained that, as to the clinical-trial and regulatory process for IH patients, there is nothing to enjoin. *Id.* at 77. Avadel noted that it intends to invest DOLLAR AMOUNT in

a clinical trial for IH patients, *id.* at 64, and underscored that there is good reason companies cannot infringe patents when they are conducting clinical trials—Congress wanted to encourage companies to conduct such trials, *id.* at 66.

Jazz acknowledged that it was not seeking to enjoin clinical trials and offered no argument that they would not be protected by the safe harbor. *Id.* at 100-01. And at the June 4, 2024 injunction hearing, the court acknowledged Avadel's clinical studies and regulatory submissions are protected by law. *Id.* at 67.[4]

Yet the district court ultimately issued an injunction undermining that statutory protection. In its August 27, 2024 opinion, the court correctly denied Jazz's motion for injunction as to narcolepsy patients because, among other things, the FDA already determined Lumryz is "clinically superior" to Xyrem and Xywav for narcolepsy, and there is a strong public interest in "protecting patient access" to Lumryz. Ex. A (Injunction Op.) at 17-21. But it granted a limited injunction as to IH patients, reasoning that "Lumryz's entrance into the market for IH would irreversibly harm Jazz's market share," *id.* at 22, and "Jazz has a pointed interest in protecting its market exclusivity," *id.* at 25. As to the public interest in Lumryz's availability for IH patients, the court—rather than waiting for FDA findings

[4] On July 31, 2024, Avadel publicly announced the first patient had been "dosed in REVITALYZ, a Phase 3 clinical study evaluating Lumryz as a potential treatment for [IH]"; the study "will enroll approximately 150 adults who are diagnosed with IH and includes an open label extension portion" whereby trial patients continue to receive treatment thereafter. https://investors.avadel.com/node/13951/pdf.

regarding the efficacy of Lumryz for IH patients—weighed the medical benefits of Lumryz's availability for itself, and determined that Lumryz does not offer "any … distinct benefits to patients with IH." *Id.* at 28. The district court therefore approved an injunction prohibiting Avadel from even "seek[ing] approval of Lumryz from the FDA for the treatment of IH." Ex. B (Injunction Order) at 3.[5] And while the order permitted Avadel to "continue to use Lumryz in currently-ongoing clinical trials," it bars Avadel from undertaking any new clinical trials for IH patients. *Id.* Neither the district court's injunction order nor its opinion supporting the order addressed the express statutory safe harbor for the "development and submission of information" to the FDA. 35 U.S.C. § 271(e)(1).

C. Jazz's Initial Letter Construing The Injunction

Avadel appealed the next day. Avadel then sent a letter to Jazz proposing a schedule for expedited appellate briefing. Ex. D (Avadel Aug. 29 Letter) at 1-2.

On August 30, Jazz responded, taking an expansive view of the injunction and threatening to interfere with (1) Avadel's ongoing clinical trial for IH patients and (2) Avadel's already-pending FDA application for pediatric narcolepsy patients. Ex. E (Jazz Letter). First, Jazz broadly asserted that any continued work on Avadel's ongoing IH clinical study is prescribed by the district court's injunction. According

[5] In contrast, the district court *denied* an injunction for narcolepsy largely based on the FDA's finding of superiority and the public interest in that treatment.

to Jazz, so long as Avadel is enjoined from seeking FDA approval for IH, the safe harbor does not protect activities for that indication. *Id*. at 2. Jazz insisted that Avadel not take any further action as to IH clinical studies, including enrolling additional subjects in ongoing studies and beginning any proposed open label extension of any ongoing study. *Id*. Second, Jazz also insisted that Avadel affirmatively withdraw its already-submitted application for FDA approval of Lumryz for pediatric patients with narcolepsy. *Id.*[6]

Because the injunction immediately threatens core activities protected under the safe harbor—especially in light of Jazz's unwarranted expansion of the injunction and implicit threat of contempt—on September 3, 2024, Avadel moved the district court for a stay pending appeal. Ex. F (D. Ct. Stay Motion). The district court promptly set expedited briefing. D.I.673.

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[6] Jazz later stated that it will *not* contend that this pediatric application contravenes the injunction. *See* Ex. I (Sept. 5 a.m. letter). So Avadel does not further address it here, but reserves the right to do so if Jazz's position changes again. By way of background, Avadel submitted its FDA application for pediatric narcolepsy patients on November 7, 2023—long before the injunction issued—and Avadel expects that FDA approval for pediatric narcolepsy could be issued within days. *See* https://investors.avadel.com/node/13741/pdf (Mar. 4, 2024) (noting "FDA target action date of September 7, 2024"); https://investors.avadel.com/node/13621/pdf (Nov. 8, 2023) (noting November 7, 2023 FDA submission). The injunction does not require Avadel to "withdraw" any previously submitted applications to FDA, and indeed expressly provides that Avadel is not barred from "making, using, and selling Lumryz" for "the treatment of narcolepsy." Ex. B at 2. Consistent with the injunction's plain terms, Avadel is entitled to market Lumryz to pediatric narcolepsy patients once FDA approves.

ARGUMENT

I. IT IS IMPRACTICABLE TO WAIT, PER CIRCUIT RULE 8(c)

Although the district court is moving promptly, Avadel believes it is not practicable to wait before asking this Court for a stay pending appeal. On its own terms, the injunction threatens Avadel's ability to pursue its ongoing clinical trial for IH. *Infra* at 17-18. And Jazz's expansive reading and implicit threat of contempt now pose an even more urgent risk: Jazz has now made clear that it would use the injunction as a cudgel to disrupt Avadel's ongoing clinical trial. *Supra* at 8-9; *infra* at 14-15, 18-19. Before filing this motion, Avadel proposed to Jazz two options to avoid the injunction's immediate impact on Avadel's ongoing clinical trial—either (1) a temporary stay or (2) Jazz would not contend Avadel's clinical trial-related activities constitute contempt during the short time it takes for the courts to resolve Avadel's motions for a stay pending appeal. *See* Ex. H (Sept. 4 letter). Jazz did not agree. *See id*.; Ex. I-K (Sept. 5. letters). Therefore, having reached an impasse, Avadel was compelled to file this motion seeking a stay pending appeal and an immediate temporary stay pending resolution of this motion.

II. THIS COURT SHOULD GRANT A STAY PENDING APPEAL

Whether to issue a stay pending appeal depends on four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay;

(3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Nken v. Holder*, 556 U.S. 418, 434 (2009) (citation omitted); *see Insulet Corp. v. Eoflow Co.*, No. 2024-1137, 2024 WL 2115888, at *1 (Fed. Cir. May 7, 2024) (per curiam) (citing *Nken*). All four favor a stay here.

A. Avadel Is Highly Likely To Succeed On The Merits Of Its Appeal

The district court's injunction is flawed on the merits, and Avadel is highly likely to succeed on appeal.[7] The injunction prohibits Avadel from (1) conducting new clinical trials in order to develop information about the efficacy and safety of Lumryz for IH patients; and (2) submitting that information to FDA as part of an application for approval from that agency. But the Patent Act expressly classifies both of those things as non-infringing. *See* 35 U.S.C. § 271(e)(1). There is no basis to enjoin that non-infringing conduct. And even setting that threshold problem aside, the district court's analysis of the factors relating to the issuance of an injunction failed in numerous respects. The injunction is likely to be reversed.

[7] Avadel's pending appeal arises from the district court's permanent injunction. The district court has not yet received the parties' post-trial motions relating to the jury verdict concerning the validity of Jazz's patent claims. Once the district court rules on those post-trial motions, Avadel may bring another appeal arising from the district court's adjudication of those motions.

1. The District Court's Injunction Clearly Exceeds Its Authority

An injunction may be entered against a defendant only "on account of a harm resulting from the defendant's wrongful conduct, not some other reason." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 640 (Fed. Cir. 2015). In a patent case, the "only acts the injunction may prohibit are infringement of the patent." *Int'l Rectifier Corp. v. IXYS Corp.*, 383 F.3d 1312, 1316 (Fed. Cir. 2004). A district court's power to grant injunctive relief "to prevent violation of patent rights" does not extend to conduct that is entirely "non-infringing." *Additive Controls & Measurement Sys., Inc. v. Flowdata, Inc.*, 986 F.2d 476, 479-80 (Fed. Cir. 1993). The injunction entered here violates that rule.

The district court's injunction prohibits Avadel from "seek[ing] approval of Lumryz from the FDA for the treatment of IH," and from using Lumryz for any such approval process, except with respect to "currently-ongoing clinical trials and studies." Ex. B at 2-3. Thus, the injunction prohibits Avadel from either undertaking any new IH clinical studies or submitting the results of any IH clinical studies (ongoing or new) to FDA pursuant to FDA's regulatory approval process. But those enjoined activities are non-infringing as a matter of clear statutory law, which specifically provides a safe harbor: it "shall not be an act of infringement" to "use" a "patented invention" if such use is "reasonably related to the *development* and *submission* of information under a Federal law which regulates the manufacture, use,

or sale of drugs." 35 U.S.C. § 271(e)(1) (emphasis added). That safe-harbor, which "provides a wide berth for the use of patented drugs in activities related to the federal regulatory process," plainly disposes of this case. *Merck*, 545 U.S. at 202.

First, the injunction's prohibition on additional clinical trials flatly contradicts the Patent Act's protection for uses "reasonably related to the development" of information for FDA approval of a new drug product. It has long been recognized that this provision categorically protects clinical trials, *see id.* at 202 n.6, including all uses "reasonably related to recruiting [assistance] for a clinical trial to support FDA approval," *Edwards Lifesciences Corp. v. Meril Life Sci. Pvt. Ltd.*, 96 F.4th 1347, 1351 (Fed. Cir. 2024).

Second, the Patent Act also makes clear that seeking FDA approval is not infringing activity. Indeed, the submission of clinical-trial information to FDA does not qualify as the "use[]" of a "patented invention," and therefore does not qualify as infringement in the first instance. 35 U.S.C. § 271(a). And if there were any doubt on that score, the safe harbor dispels it: "uses reasonably related to the … submission of information" to the FDA are non-infringing. *Id.* § 271(e)(1). An application for FDA approval *is* a "submission of information" to the FDA, so it is necessarily non-infringing. *See Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997) (safe harbor protects any "use … reasonably related to FDA approval"). The whole point of the safe harbor is to protect all "activities necessary

to obtain regulatory approval." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990). And what is clear as a matter of statute is also mandatory as a matter of constitutional law: Avadel has a First Amendment right to petition "administrative agencies" like the FDA, and it would be "destructive of" that right to prohibit Avadel from advocating its "points of view" with the FDA. *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11 (1972). A counter-textual reading of the Patent Act that permitted the district court to enjoin Avadel from seeking FDA approval of a drug would raise serious constitutional problems.

These defects with the injunction are sufficient on their own to show that Avadel is likely to prevail on the merits of its appeal.

2. Jazz's Arguments For The Injunction Are Meritless And Highlight Why Avadel's Appeal Will Succeed

In its communications with Avadel, Jazz has advanced arguments in defense of the district court's injunction that cannot be reconciled with the injunction itself and that ultimately fail as a matter of law.

In particular, Jazz asserted that the injunction requires Avadel to stop enrolling additional subjects in its ongoing REVITALYZ clinical trial and to deprive REVITALYZ participants of any open label extension of that study. Ex. E at 2. That assertion contradicts the face of the injunction, which expressly permits Avadel to pursue any "currently-ongoing clinical trials and studies." Ex. B at 2-3. Avadel must enroll new participants in REVITALYZ in order to complete that study, *see*

Ex. G (Gudeman Decl. ¶¶ 5-6), and those participants' enrollment in the study's open label extension is a component of the study itself, *id.* ¶ 9. And setting that point aside, the enrollment of new participants and the open label extension components are clearly non-infringing, since they are "reasonably related to recruiting" participants in "a clinical trial to support FDA approval." *Edwards Lifesciences*, 96 F.4th at 1351; *see* Ex. G (Gudeman Decl. ¶ 9). Jazz's justification for its position is that the safe harbor protects only activities undertaken towards obtaining FDA approval and therefore does not apply to activities undertaken for securing FDA approval of Lumryz for IH patients because the injunction prevents Avadel from seeking FDA approval for IH. Ex. E at 2 (citation omitted).

That circular logic fails: Avadel is entitled to seek FDA approval and to undertake all "activities necessary to obtain regulatory approval." *Lilly*, 496 U.S. at 671. And the safe harbor applies "irrespective of the stage of research and even if the information is never ultimately submitted to the FDA." *Edwards Lifesciences*, 96 F.4th at 1351. Importantly, even if the injunction is never overturned, Avadel would unquestionably be able to proceed with marketing of IH, upon FDA approval, once the patent expires. The safe harbor protects Avadel's clinical studies. Jazz's attempt to leverage the already-flawed injunction to sweep in still more protected safe harbor activity underscores that Avadel is likely to succeed on appeal.

3. Neither The Equities Nor The Public Interest Support The District Court's Injunction

Avadel is also likely to succeed on appeal because the district court's analysis of irreparable harm, the balance of the equities, and the public interest was deeply flawed. The district court reasoned, for instance, that "Lumryz's entrance into the market for IH would irreversibly harm Jazz's market share and damage its ability to build its reputation as the exclusive market leader." Ex. A at 22. It therefore held that "Jazz would suffer irreparable injury if Avadel is not enjoined from seeking FDA approval and marketing Lumryz for IH." *Id.* This does not follow. Accepting *arguendo* the district court's findings regarding the irreparable harm Jazz might suffer if Avadel *markets* Lumryz to IH patients, that does not establish Jazz would suffer irreparable harm merely from an application for FDA approval. The district court made *no* findings establishing that mere submission of an application for FDA approval would irreparably harm Jazz. And its terse analysis of the balance of the equities failed for the same reason. *Id.* at 25.

Similarly, the district court's public-interest analysis wrongly preempted the FDA's role in considering the efficacy and potential clinical superiority of Lumryz vis-à-vis other IH drugs. *See id.* at 25-29. It is impossible to analyze the public interest in the market availability of Lumryz for IH patients without first giving the FDA the chance to review the scientific evidence. But that is precisely what the

injunction forbids. The district court's upside-down analysis of the public interest is likely to be rejected on appeal.

B. Avadel Will Suffer Irreparable Harm In The Absence Of A Stay

Not only is Avadel likely to succeed on the merits of its appeal, but absent a stay, the injunction will irreparably harm Avadel by restraining statutorily protected research regarding IH and prohibiting Avadel from seeking an IH indication for Lumryz. As explained by Dr. Jennifer Gudeman, Avadel's Vice President for Medical and Clinical Affairs, the injunction imposes several immediate (and irreparable) practical harms.

First, the injunction—notwithstanding its carveout for any "ongoing" clinical trial—presents a serious risk of impairing Avadel's recently commenced REVITALYZ trial, which is Avadel's first step towards supporting an eventual application for an IH indication for Lumryz. Ex. G (Gudeman Decl. ¶ 4). Thus, even though Avadel is likely to prevail on appeal, it will (absent a stay) suffer irreparable harm with respect to its ongoing clinical trial while its appeal is pending. To complete a clinical trial, Avadel must enroll a sufficient number of patients. *Id.* ¶ 5. Concerns over legal impediments to clinical trials can damage the confidence of physicians who would otherwise recommend that their patients enroll. *Id.* ¶¶ 8-9. Those who become aware of the injunction may have concerns that the study is unsafe, which makes recruitment more difficult. *Id.* Thus, the injunction presents a

substantial risk of disrupting the ongoing REVITALYZ trial, or at least delaying its progress. Every day that the REVITALYZ trial is delayed as a result of the injunction is a form of irreparable harm to Avadel's reputation and one of its core business objectives: to place Lumryz on the market for IH patients as quickly as possible. *Id.* ¶ 8. And that harm does not encompass the further harm that Avadel will encounter if it needs to undertake further clinical studies of Lumryz and is prevented from doing so by the plain terms of the district court's injunction. *Id.* ¶¶ 9-10.

Second, Avadel's harm is all the more clear and pressing given Jazz's view of the scope of the injunction. As noted, Jazz asserts that the injunction prohibits Avadel from even enrolling new IH patients in its clinical study or continuing any open label extension for currently enrolled study participants. Ex. E at 2. Jazz is threating Avadel with contempt if Avadel does not comply with Jazz's inflated view of the injunction—which could likewise imperil Avadel's current clinical trial. *See id.*; Ex. H-K. Halting enrollment in the REVITALYZ trial would pose irreparable harms to Avadel's reputation with researchers and patients, and would significantly and irreparably delay the progress of the REVITALYZ trial. Ex. G (Gudeman Decl. ¶¶ 6-8). And open label extensions—which allow clinical-trial participants to continue using a trial drug following completion of the clinical trial—are a valuable recruiting tool that promote enrollment in clinical trials. *Id.* ¶ 10. If the injunction

prohibited open label extensions, that too would result in irreparable harm to Avadel. *Id.* ¶ 9.

Third, the injunction treads on Avadel's First Amendment right to petition the FDA—and that injury is irreparable per se. A "loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Kim v. Hanlon*, 99 F.4th 140, 159 (3d Cir. 2024) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). This Court should issue a stay pending appeal so that these clear, immediate, and irreparable harms to Avadel are averted.

C. A Stay Pending Appeal Will Not Harm Jazz

Whereas the denial of a stay is likely to visit irreparable harms on Avadel, Jazz cannot assert that it will suffer any harm (irreparable or otherwise) from the issuance of a stay pending appeal. Even absent an injunction, the earliest that Avadel could possibly apply for FDA approval to market Lumryz to IH patients is DATE DATE; and the earliest it could *receive* FDA approval is DATE DATE from now. *See* Ex. G (Gudeman Decl. ¶ 10). This appeal is sure to be resolved well before such approval, particularly given Avadel's motion for expedition, filed concurrently with this motion. Thus, Avadel cannot begin competing against Jazz in the market for IH patients until after this appeal is resolved. All that a stay would do is to permit Avadel to undertake clinical trial work and to share the results with the FDA during the course of this appeal. That non-infringing conduct cannot harm

Jazz. But, as explained above, if the Court declines to stay the injunction and Avadel ultimately prevails on appeal, Avadel will be irreparably, and needlessly, harmed.

D. The Public Interest Favors A Stay Pending Appeal

Finally, the public interest clearly weighs in favor of a stay. Clinical trials add to the store of human knowledge—particularly where such discoveries identify safe and effective clinical treatments. That is why Congress expressly shielded them from the operation of the patent laws. *See* 35 U.S.C. § 271(e)(1). The public has every interest in the ability of drug manufacturers to develop information about the efficacy and safety of their drug products and to share that information with the FDA. *Cf. Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989) (noting the "public interest in the development … of reasonably priced prescription drug products"). A stay pending appeal will merely permit Avadel to continue with its clinical trials for IH patients, to share the results of those trials, and eventually to seek FDA approval for IH. There is no plausible public interest in preventing or delaying Avadel from undertaking those trials and presenting their results to FDA. For that reason, too, this Court should issue a stay pending appeal.

III. THIS COURT SHOULD GRANT A TEMPORARY STAY WHILE IT CONSIDERS THIS MOTION

In cases involving a motion for stay pending appeal, this Court may issue an interim stay to preserve the status quo pending consideration of the motion. *See Apple Inc. v. ITC*, No. 24-1285 (Fed. Cir. Dec. 27, 2023) ("interim stay … while the court considers the motion for stay pending appeal"); *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 396 F. App'x 686 (Fed. Cir. 2010). Indeed, this Court did so in Jazz's favor in the earlier appeal in this action. *See Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC*, No. 23-1186 (Fed. Cir. Nov. 29, 2022), ECF No. 10. There, this Court recognized that the district court "appears to be working towards a prompt resolution of that motion." *Id.* The same is true here.

The district court ordered expedited briefing on the motion to stay—it is "working towards a prompt resolution." *Id.*; *see* D.I.673. Also, Avadel proposed to Jazz ways to avoid the immediate impacts of Jazz's overbroad view of the injunction at least during the short period in which the district court and this Court consider the stay motions; but the parties reached an impasse. *See* Exs. H-K; *supra* at 10. Accordingly, this Court should temporarily stay the injunction to maintain the status quo and ensure the injunction does not disrupt Avadel's ongoing clinical trial for IH patients in the coming days. Jazz will suffer no harm from this temporary stay while the stay motions are resolved.

CONCLUSION

The district court's injunction should be stayed pending appeal. In the interim, this Court should grant a temporary stay pending consideration of this motion.

Dated: September 6, 2024

Respectfully submitted,

/s/ Gabriel K. Bell

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g)(1) and Federal Circuit Rule 32(b)(3), I hereby certify that the foregoing motion complies with the type-volume limitation in Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 5,176 words, excluding the exempted parts under Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

I further certify that this response complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because this response was prepared using Microsoft Word 365 in 14-point Times New Roman font.

/s/ Gabriel K. Bell
Gabriel K. Bell

Counsel for Appellee
Avadel CNS Pharmaceuticals, LLC

CERTIFICATE OF COMPLIANCE WITH RULE 25.1(e)(2)

I hereby certify that the foregoing complies with the limitations set forth in Federal Circuit Rule 25.1(d)(1)(A) and contains seven unique words (including numbers and images) marked as confidential.

Date: September 6, 2024

/s/ Gabriel K. Bell
Gabriel K. Bell

TABLE OF CONTENTS

Pursuant to Federal Circuit Rule 25.1(e)(1)(B), Defendant-Appellant provides the following description of the general nature of the material redacted in the nonconfidential version of its motion:

The material omitted on Exhibits A, C-H relates to confidential business information subject to a protective order.

I. PROTECTIVE ORDERS (PO) IN ACCORDANCE WITH FED. CIR. R. 25.1(e)(1)(A)

Ex. No.	Description
PO-1	Protective Order (Oct. 19, 2021), ECF No. 42[1]
PO-2	Order Modifying to October 19, 2021 Protective Order (Jan. 4, 2022), ECF No. 74
PO-3	Order Further Modifying to October 19, 2021 Protective Order (Apr. 7, 2022), ECF No. 96

II. RECORD DOCUMENTS IN ACCORDANCE WITH FED. R. APP. P. 27(a)(2)(B)

Ex. No.	Description
A	Memorandum Opinion on Plaintiff's Motion for a Permanent Injunction (Aug. 27, 2024), ECF No. 665 —SEALED —REDACTED, ECF No. 674-1

[1] ECF numbers in this Table of Contents refer to the documents filed in *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*, Case No. 1:21-cv-00691-GBW (D. Del.).

Ex. No.	Description
B	Order on Plaintiff's Motion for a Permanent Injunction (Aug. 27, 2024), ECF No. 666
C	Transcript of Hearing on Plaintiff's Motion for a Permanent Injunction (June 6, 2024) (excerpts), ECF No. 671-1 —SEALED
D	Avadel CNS Pharmaceuticals, LLC Letter (Aug. 29, 2024), ECF No. 671-1 —SEALED
E	Jazz Pharmaceuticals, Inc. Letter (Aug. 30, 2024), ECF No. 671-1 —SEALED
F	Defendant's Emergency Motion for Stay Pending Appeal (Sept. 3, 2024), ECF No. 670 —SEALED
G	Gudeman Declaration in Support of Defendant's Emergency Motion for Stay Pending Appeal (Sept. 3, 2024), ECF No. 672 —SEALED
H	Avadel CNS Pharmaceuticals, LLC Letter (Sept. 4, 2024) —SEALED
I	Jazz Pharmaceuticals, Inc. Letter (Sept. 5, 2024) —SEALED
J	Avadel CNS Pharmaceuticals, LLC Letter (Sept. 5, 2024)
K	Jazz Pharmaceuticals, Inc. Letter (Sept. 5, 2024)

EXHIBIT PO-1

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 21-691 (MN)
	)	
AVADEL PHARMACEUTICALS PLC, AVADEL US HOLDINGS, INC., AVADEL SPECIALTY PHARMACEUTICALS, LLC, AVADEL LEGACY PHARMACEUTICALS, LLC, AVADEL MANAGEMENT CORPORATION and AVADEL CNS PHARMACEUTICALS LLC,	)	
	)	
Defendants.	)	

STIPULATED PROTECTIVE ORDER

WHEREAS, discovery in the above-entitled action ("Action") may involve the disclosure of certain documents, things and information in the possession, custody or control of Plaintiff Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals"), Defendants Avadel Pharmaceuticals plc, Avadel US Holdings, Inc., Avadel Specialty Pharmaceuticals, LLC, Avadel Legacy Pharmaceuticals, LLC, Avadel Management Corporation, and Avadel CNS Pharmaceuticals LLC (collectively "Avadel"), or non-parties that constitute or contain trade secrets or other confidential research, development or commercial information within the meaning of Rule 26(c) of the Federal Rules of Civil Procedure ("Fed. R. Civ. P.") and as further set forth below;

WHEREAS, the parties, through counsel, stipulate to the entry of this Protective Order to prevent unnecessary dissemination or disclosure of such confidential information; and

WHEREAS, the parties, through counsel, stipulate that good cause exists for the entry of this Protective Order pursuant to Fed. R. Civ. P. 26(c) to protect against improper disclosure or use of confidential information produced or disclosed in this case.

IT IS HEREBY STIPULATED AND AGREED, SUBJECT TO THE APPROVAL AND ORDER OF THE COURT, as follows:

1. **Scope of Protective Order**. This Protective Order shall apply to all information, documents and things produced or within the scope of discovery in this Action, including, without limitation, all testimony adduced and documents and things marked as exhibits at depositions, hearings, and at trial, documents or things produced in response to requests for the production of documents and things, answers to interrogatories, responses to requests for admission and all other discovery taken pursuant to the Federal Rules of Civil Procedure, correspondence between counsel, as well as hearing or trial transcripts, matters in evidence, and any other information furnished, directly or indirectly, by or on behalf of any party to this Action or any THIRD PARTY to the extent such material is designated "CONFIDENTIAL INFORMATION" or "HIGHLY CONFIDENTIAL INFORMATION" in accordance with ¶¶ 2 and 4 of this Protective Order.

This Protective Order shall also govern any designated record of information produced in this action pursuant to required disclosures under any federal procedural rule or District of Delaware local rule, and any supplementary disclosures thereto.

2. **Definitions**. The terms "CONFIDENTIAL INFORMATION," "HIGHLY CONFIDENTIAL INFORMATION" and "THIRD PARTY" or "THIRD PARTIES," as used herein, shall mean the following:

a. "CONFIDENTIAL INFORMATION" means any tangible thing or oral testimony that contains or reveals what a party or THIRD PARTY considers to be its trade secret, business confidential, or proprietary research, development, commercial, or financial information. It may include, without limitation, documents produced in this action, during formal discovery or otherwise; information of non-parties which

the producing or designating party is under an obligation to maintain in confidence; initial disclosures; answers to interrogatories and responses to requests for admission or other discovery requests; deposition or hearing transcripts; affidavits; exhibits; experts' reports; memoranda of law; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all copies, abstracts, excerpts, analyses, notes or other writings that contain, reflect, reveal or otherwise disclose such confidential information shall also be deemed "CONFIDENTIAL INFORMATION." Information originally designated as "CONFIDENTIAL INFORMATION" shall not retain that status after any ruling by the Court denying such status to it. Each party shall act ii good faith in designating information as "CONFIDENTIAL INFORMATION."

b. "HIGHLY CONFIDENTIAL INFORMATION" means all information regarding (i) confidential, highly sensitive, and/or proprietary information pertaining to marketing, sales, revenues, profits, forecasts, or business plans or strategies for any existing products or products in development; (ii) past, current or future products other than sodium oxybate-containing drug products, (iii) past, current or future plans regarding treatment indications for sodium oxybate-containing drug products other than the treatment indications for which FDA approval is or has been sought; and (iv) scientific or technical information relating to, referring to, or concerning Xyrem®, Xywav™, FT218, Drug Master Files ("DMF") related in any way to Xyrem®, Xywav™ and/or FT218, and/or the associated products (including compositions, methods, uses, or processes) that constitute or reflect trade secrets or other proprietary information, including, but not limited to, draft patent

applications, invention disclosures, non-public patent filings; confidential research, development, testing and studies relating to drug products, methods, uses or processes; any correspondence or draft correspondence with the FDA regarding FT218; any research, development, testing, analysis and/or studies, including analytical data relating to any chemical materials used to produce a sodium oxybate-containing composition that the producing party reasonably believes the disclosure of which is likely to cause harm to the competitive position of the party producing the information of could be used in patent prosecution by the party receiving the information to the competitive disadvantage of the party producing the information. It may include, without limitation, documents produced in the actions, during formal discovery or otherwise; information of non-parties which the producing or designating party is under an obligation to maintain in confidence; initial disclosures; answers to interrogatories and responses to requests for admission or other discovery requests; deposition or hearing transcripts; affidavits; exhibits; experts' reports; memoranda of law; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all drafts, copies, abstracts, excerpts, analyses, notes or other writings that contain, reflect, reveal or otherwise disclose such highly confidential information shall also be deemed "HIGHLY CONFIDENTIAL INFORMATION." Information originally designated as "HIGHLY CONFIDENTIAL INFORMATION" shall not retain that status after any ruling by the Court denying such status to it. Each party shall act in good faith in designating information as "HIGHLY CONFIDENTIAL INFORMATION."

c. "THIRD PARTY" or "THIRD PARTIES" means any person or entity who is not a named party in this Action.

3. **THIRD PARTIES under the Protective Order**. If a THIRD PARTY provides discovery to any party in connection with this Action, and if the THIRD PARTY so elects, then the provisions of this Protective Order shall apply to such discovery and the parties will treat all information that is produced by such THIRD PARTY in accordance with the terms of this Protective Order to the extent it is designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. Under such circumstances, the THIRD PARTY shall have the same rights and obligations under this Protective Order as held by the parties to this Action. Because third parties may be requested to produce documents containing information that a party considers CONFIDENTIAL or HIGHLY CONFIDENTIAL, at the request of any party all documents produced by a third party in this action shall be treated as if designated HIGHLY CONFIDENTIAL under this Protective Order for a period of seven (7) days after production in order to allow the parties time to review the documents and make any appropriate designations hereunder.

4. **Designation.** Each party shall have the right to designate information as CONFIDENTIAL or HIGHLY CONFIDENTIAL subject to this Protective Order. To the extent that material is designated CONFIDENTIAL or HIGHLY CONFIDENTIAL, such material shall only be revealed to or used by limited categories of individuals, as provided for in ¶¶ 13-14, and shall not be communicated in any manner, either directly or indirectly, to any person or entity except as provided herein. Any copies of such material, abstracts, summaries or information derived therefrom, and any notes or other records regarding the contents thereof, shall also be deemed CONFIDENTIAL or HIGHLY CONFIDENTIAL (consistent with the designation of the

originals), and the same terms regarding confidentiality of these materials shall apply as to the originals. The procedures for designating materials as CONFIDENTIAL or HIGHLY CONFIDENTIAL are as follows:

a. **Designation of Documents and Things**. The producing party shall label or mark each page of each document and thing that constitutes or contains CONFIDENTIAL INFORMATION with the legend "CONFIDENTIAL," or otherwise mark or designate in writing the materials as CONFIDENTIAL INFORMATION and subject to the Protective Order when the document or thing is produced to the receiving party. The producing party shall label or mark each page of each document and thing that constitutes or contains HIGHLY CONFIDENTIAL INFORMATION with the legend "HIGHLY CONFIDENTIAL," or otherwise mark or designate in writing the materials as HIGHLY CONFIDENTIAL INFORMATION and subject to the Protective Order when the document or thing is produced to the receiving party.

Anything that cannot be so marked shall be designated by placing the appropriate legend on a container or package in which the thing is produced or on a tag attached thereto. Each page of each document and each thing produced pursuant to discovery in this Action shall also bear a unique identifying number.

Documents and things produced without a legend designating the material as either CONFIDENTIAL or HIGHLY CONFIDENTIAL shall not be subject to this Protective Order unless otherwise agreed by the parties, ordered by the Court, or otherwise designated as either CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION in accordance with the provision of ¶ 9 of this Protective Order. Inspection of documents or things by any party shall be conducted by persons eligible

under ¶¶ 13-14 below. Such persons shall initially treat all information obtained during or from any inspection as containing HIGHLY CONFIDENTIAL INFORMATION until such time as copies of documents or things from the inspection are produced, and, thereafter, such produced documents and things shall be treated in accordance with any confidentiality designation appearing on the document or thing at the time of its production.

Documents and things produced or made available for inspection may be subject to redaction, in good faith by the producing party, of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION that is neither relevant to the subject of this litigation nor reasonably calculated to lead to the discovery of admissible evidence, or is subject to the attorney-client privilege, work-product immunity, or other applicable privilege or immunity from production recognized under the Federal Rules of Evidence. Each such redaction, regardless of size, shall be clearly labeled. This Paragraph shall not be construed as a waiver of any party's right to seek disclosure of redacted information. All documents redacted based on attorney-client privilege or work-product immunity shall be listed on a privilege log in accordance with Federal Rule of Civil Procedure 26(b)(5) and exchanged at a mutually agreeable date and time.

b. **Designation of Written Discovery**. Pleadings, Interrogatories, Requests for Admission, Written Testimony, and any other written discovery which in good faith are deemed by the disclosing party to contain or comprise CONFIDENTIAL INFORMATION will be so identified and marked "CONFIDENTIAL" by that party. Pleadings, Interrogatories, Requests for Admission, Written Testimony, and any other written discovery which in good faith are deemed by the disclosing party to contain or

comprise HIGHLY CONFIDENTIAL INFORMATION will be so identified and marked "HIGHLY CONFIDENTIAL" by that party.

c. **Designation of Deposition Transcripts.** Deposition transcripts containing either CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION may be designated as subject to this Protective Order either on the record during the deposition or by providing written notice within thirty (30) days following receipt of the official transcripts of the deposition.

All deposition transcripts not previously designated shall be deemed to be, and shall be treated as HIGHLY CONFIDENTIAL for a period of thirty (30) days after receipt of the official transcript of the deposition by the designating party, and the transcript shall not be disclosed during such time by a non-designating party to persons other than those persons qualified to receive such information pursuant to this Protective Order. After thirty (30) days after receipt by the designating party, if a transcript has not been designated, the aforementioned testimony shall no longer be treated as HIGHLY CONFIDENTIAL INFORMATION unless the parties otherwise agree.

The parties agree to mark at least the first page of all copies of deposition transcripts that contain testimony, or that append exhibits, designated as either CONFIDENTIAL or HIGHLY CONFIDENTIAL with the legend "CONFIDENTIAL INFORMATION" "HIGHLY CONFIDENTIAL INFORMATION," commensurate with the designation. This paragraph does not limit any party's right to challenge any presumptive designation or preclude a producing party from designating testimony or transcripts as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

d. **Designation of Hearing Testimony or Argument.** With respect to testimony elicited during hearings and other proceedings, whenever counsel for any party deems that any question or line of questioning calls for the disclosure of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, counsel may ask the Court to designate on the record that the disclosure is subject to confidentiality restrictions. Whenever matter designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is to be discussed in a hearing or other proceeding, any party claiming such confidentiality may ask the Court to have excluded from the hearing or other proceeding any person who is not entitled under this Order to receive information so designated.

5. **Limitations on Attendance at Depositions**. Counsel for a producing party may request that all persons other than the witness, counsel for the witness (who signs the Undertaking attached as Exhibit A if a non-party witness), the court reporter, and those individuals specified in ¶¶ 13-14, as applicable, leave the deposition room during the portion of the deposition that inquires about or discloses subject matter that counsel for the producing party believes to be CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION hereunder. If individuals other than those specified in the previous sentence fail to leave the deposition room during any portion of the deposition that inquires about or discloses what counsel for the producing party believes to be CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, counsel for the producing party may seek relief from the appropriate Court and, pending resolution of its request for relief, instruct the witness not to answer questions relating to, or limit disclosure of, the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION at issue.

6. **Limitations on Attendance at Hearings or Trial.** Counsel shall confer with the Court regarding any requested procedures to protect the confidentiality of material marked, labeled, or otherwise designated as either CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION that a party or any of its witnesses may use, refer to, disclose, or admit into evidence during trial or any hearing in this Action. Counsel may request that attendance at a hearing or at a trial session in this Action at which material designated CONFIDENTIAL INFORMATION will be used or disclosed be limited for the time period during which either CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION will be used or disclosed to individuals entitled to have access to such materials under the terms of this Protective Order.

7. **Proper Use and Disclosure of Designated Information.** Subject to the limitations and restrictions of this Protective Order and any further order regarding confidentiality that the Court may enter, material marked, labeled or otherwise designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION as described in this Protective Order may be used solely to prepare for and conduct discovery, to prepare for trial and to support or oppose any motion in this Action, and may be used in testimony at trial, offered into evidence at trial and/or hearings on motions subject to such procedures mandated by the Court. Nothing herein shall be construed to affect in any way the admissibility of any document, testimony or other evidence at trial.

Material designated as either CONFIDENTIAL or HIGHLY CONFIDENTIAL, and all information derived therefrom, shall be used only by persons permitted access to such information under this Protective Order, shall not be disclosed by the receiving parties to any party or person not entitled under this Protective Order to have access to such material, and shall not be used by

the receiving parties for any purpose other than in connection with this action, including without limitation for any research, development, manufacture, patent prosecution, post-grant review, post-grant patent challenges (*e.g.*, inter partes review or supplemental examination), financial, commercial, marketing, regulatory, business, or other competitive purpose (except for settlement of the above-captioned case).

For the length of this litigation plus one year after a final, non-appealable judgment in this litigation, any person receiving information designated as HIGHLY CONFIDENTIAL INFORMATION under this Order may not engage, formally or informally, directly or indirectly, in any U.S. or foreign patent prosecution (as used herein, "patent prosecution" means drafting and/or amending patent claims, but is not intended to preclude involvement in reexaminations, oppositions, inter partes reviews, or similar post-grant proceedings before the U.S. Patent and Trademark Office or any foreign patent office as long as such individuals are not involved directly or indirectly in drafting or amending patent claims or providing recommendations regarding the drafting or amending of patent claims) for any patents or patent applications that, if issued: i) could be listed in the Orange Book for Xyrem®; ii) could cover once-nightly formulations of sodium oxybate or components thereof; iii) could cover methods of treatment using once-nightly formulations of sodium oxybate; iv) could cover any process, machine, manufacture, or composition of matter related to the distribution of sensitive drugs, including oxybate or v) could cover processes for manufacturing once-nightly formulations of sodium oxybate. The patent prosecution bar in this paragraph shall not apply to patent applications containing claims (either in the application as filed or as amended) that are limited to: (1) methods of treating diseases or conditions other than narcolepsy or any symptoms thereof with administration of sodium oxybate

or GHB or a salt thereof; or (2) non-once-nightly formulations containing sodium oxybate or GHB or a salt thereof that could not cover a once-nightly formulation or any components thereof.

For the length of this litigation plus one year after a final, non-appealable judgment in this litigation, any person receiving information designated as HIGHLY CONFIDENTIAL INFORMATION may not be involved, directly or indirectly, in drafting or amending any petition or other correspondence before or involving the FDA or equivalent foreign agency concerning any once-nightly sodium oxybate product. Notwithstanding the foregoing sentence, nothing in this paragraph prevents the person from performing work before the FDA or equivalent foreign agency solely for obtaining or maintaining approval of the Receiving Party's own new drug application provided that no HIGHLY CONFIDENTIAL INFORMATION of the Producing Party is used or disclosed.

Absent written consent of the producing parties or further order of this Court, all persons receiving information designated either CONFIDENTIAL or HIGHLY CONFIDENTIAL are expressly prohibited from using or disclosing such information in connection with any practice before or communication with (post-grant patent challenges, citizens petitions, and other filings) the United States Patent and Trademark Office, the FDA, the United States Pharmacopoeia, or their counterpart organizations in any foreign jurisdiction.

8. **Storage of CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION**. The recipient of any CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION shall maintain such information in a secure and safe manner and shall exercise the same standard of due and proper care with respect to the storage, custody, use and/or dissemination of such information as is exercised by the recipient with respect to his/her/its own proprietary information.

9. **Inadvertent Production of CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION**. If a party inadvertently produces or provides discovery of any CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION without labeling or marking it as provided in this Protective Order, the producing party may give written notice to the receiving party or parties, within ten (10) business days after becoming aware of the inadvertent production, that the document, thing or other discovery information, response or testimony is CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, as the case may be, and should be treated as such in accordance with the provisions of this Protective Order. The producing party will also provide copies of the properly marked information (*e.g.*, documents, discovery responses, transcripts, things, and/or all other information within the scope of this Protective Order). Upon receipt of such notice and properly marked information, the receiving party or parties shall return or destroy said unmarked or incorrectly marked information to the extent practicable and not retain copies thereof, and shall undertake best efforts to correct any disclosure of such information contrary to the redesignation. Prior to receipt of such notice, disclosure of such documents, things, information, responses and testimony to persons not authorized to receive CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, as the case may be, shall not be deemed a violation of this Protective Order.

10. **Limitations on Advice to Clients**. It is understood that counsel for a party may give advice and opinions to his or her client based on his or her evaluation of designated CONFIDENTIAL INFORMATION and/or HIGHLY CONFIDENTIAL INFORMATION received by the party, provided that such rendering of advice and opinions shall not reveal the

content of such information, except by prior written agreement with counsel for the producing party.

11. **Discovery of THIRD PARTY Information**. A producing party may redact the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION of a THIRD PARTY that is in its possession where the producing party is under an obligation not to disclose such information, provided that the producing party shall identify the THIRD PARTY to the receiving party and shall not impede discovery by the receiving party from said THIRD PARTY.

12. **Inadvertent Production of Privileged or Work Product Information**. When the inadvertent or mistaken disclosure of any information, document or thing protected by privilege or work-product protection is discovered by the producing party and brought to the attention of the receiving party, the receiving party's treatment of such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5)(B) and Federal Rule of Evidence 502(b). For purposes of any analysis under Federal Rule of Evidence 502(b), if the producing party certifies in good faith that the production was inadvertent and reasonable steps were taken to prevent disclosure, then it shall be treated as such.

When making a claim of privilege, the producing party shall include a privilege log entry reflecting the privileged material. Upon receipt of a claim of privilege, the receiving party shall destroy all copies of the privileged material. If the receiving party wishes to contest a claim of privilege, the receiving party shall notify the producing party within seven (7) days. Thereafter, the parties shall meet and confer promptly and, if the parties are unable to resolve the dispute, the parties shall contact the Court's Judicial Administrator to schedule an argument to resolve the dispute pursuant to the Court's Rule 16 Scheduling Order in this case. The receiving party shall

not retain a copy of the privileged material for the purposes of challenging the claim, and any challenge shall be based on the privilege log entry provided by the producing party.

13. **Access to CONFIDENTIAL INFORMATION.** Material marked, labeled or otherwise designated CONFIDENTIAL INFORMATION as described in this Protective Order shall be deemed and treated as CONFIDENTIAL INFORMATION hereunder, unless and until the Court rules to the contrary, and access thereto or disclosure thereof shall be limited, unless and until the Court rules that there may be further disclosure, to the following individuals:

a. Quinn Emanuel Urquhart & Sullivan, LLP and Morris, Nichols, Arsht & Tunnell LLP, litigation counsel of record for Plaintiff Jazz Pharmaceuticals, and their partners, associates, attorneys, data entry, information processing, computer support, artist, translating, stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require access to material designated CONFIDENTIAL INFORMATION.

b. Two (2) in-house counsel for Jazz Pharmaceuticals, to be designated at a later time, and clerical staff (including paralegals) working directly with them (who sign the Undertaking attached as Exhibit A), whose duties and responsibilities require access to material designated CONFIDENTIAL INFORMATION. Jazz Pharmaceuticals represents that the designated in-house counsel , after receipt of CONFIDENTIAL INFORMATION, and in addition to the other terms of this Protective Order, shall not disclose to the FDA, the U.S. Patent and Trademark Office, or any nonparty, any CONFIDENTIAL INFORMATION. Notwithstanding the foregoing provisions, in-house counsel shall be permitted to advise Jazz Pharmaceuticals regarding legal strategy and the pending litigation; provided, however, that the CONFIDENTIAL INFORMATION is not thereby disclosed.

c. Latham & Watkins LLP, Durie Tangri LLP, and McCarter & English, LLP, litigation counsel of record for Defendant Avadel, and their partners, associates, attorneys, data entry, information processing, computer support, artist, translating, stenographic, clerical, and paralegal employees or agents whose duties and responsibilities require access to material designated CONFIDENTIAL INFORMATION.

d. Two (2) in-house counsel for Avadel, to be designated at a later time, and clerical staff (including paralegals) working directly with them (who sign the Undertaking attached as Exhibit A), whose duties and responsibilities require access to material designated CONFIDENTIAL INFORMATION. Avadel represents that the designated in-house counsel, after receipt of CONFIDENTIAL INFORMATION, and in addition to the other terms of this Protective Order, shall not disclose to the FDA, the U.S. Patent and Trademark Office, or any nonparty, any CONFIDENTIAL INFORMATION. Notwithstanding the foregoing provisions, in-house counsel shall be permitted to advise Avadel regarding legal strategy and the pending litigation; provided, however, that the CONFIDENTIAL INFORMATION is not thereby disclosed.

e. Outside consultants or experts and their staffs retained by the parties or their attorneys for purposes of this action, who are not objected to pursuant to ¶ 14, and who first agree to be bound by the terms of this Protective Order;

f. The Court before which this Action is pending and their authorized staff court reporters;

g. Court reporters, videographers, and their respective staffs employed in connection with this action;

h. Any interpreter and any typist or transcriber used by the interpreter, who first agrees to be bound by the terms of this Protective Order;

i. Any Third Party Vendors as defined below, who first agree to be bound by the terms of this Protective Order; and

j. Any other person as to whom the parties agree in writing.

14. **Access to HIGHLY CONFIDENTIAL INFORMATION.** Material marked, labeled or otherwise designated HIGHLY CONFIDENTIAL INFORMATION as described in this Protective Order shall be deemed and treated as HIGHLY CONFIDENTIAL INFORMATION hereunder, unless and until the Court rules to the contrary, and access thereto or disclosure thereof shall be limited, unless and until the Court rules that there may be further disclosure, to the persons identified in ¶ 13.a., ¶ 13.c. and ¶ 13.e-j. In addition, one individual eligible to receive CONFIDENTIAL INFORMATION pursuant to ¶ 13.b. and ¶ 13.d. shall be permitted access to HIGHLY CONFIDENTIAL INFORMATION; provided, however, that such individual shall be disclosed to the producing party's outside counsel before any HIGHLY CONFIDENTIAL INFORMATION is shared with such person. For the avoidance of doubt, nothing herein precludes the parties from agreeing in writing to allow additional persons eligible to receive CONFIDENTIAL INFORMATION pursuant to ¶ 13.b. and ¶ 13.d. access to a producing party's HIGHLY CONFIDENTIAL INFORMATION.

15. **Retention of Experts and Outside Consultants**. Disclosure of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL shall not be made to any such outside consultant described in ¶ 13.e. for a period of seven (7) days after serving the party providing discovery with a signed Undertaking in the form of the annexed Exhibit A, a list of all cases in which, during the

previous five (5) years, the expert or consultant has provided a written expert report or testified at trial or by deposition, and a current curriculum vitae of the outside consultant.

Counsel for the party providing discovery may, within the seven (7) day period, serve a notice of objection if a reasonable basis for such objection exists. If the notice is served, no CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION will be disclosed to such outside consultant. Within seven (7) days after service of the objection, if the parties are unable to reach any agreement over the disclosure of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION to the expert or consultant, the parties shall contact the Court's Judicial Administrator to schedule an argument to resolve the dispute pursuant to the Court's Rule 16 Scheduling Order in this case. Until the dispute is resolved, no CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall be disclosed to the outside expert or consultant until the Court rules or the parties agree that such disclosure may be made. Failure to contact the Court's Judicial Administrator to schedule an argument to resolve the dispute within the seven (7) day period shall operate as a waiver of this objection, unless the parties agree in writing to extend this deadline while meeting and conferring regarding the objection.

16. **Third Party Vendors**. Counsel may use the services of THIRD PARTY vendors, contractors or agents ("Third Party Vendors") to provide services such as document review, electronic discovery support, computerized legal support, copying and computer services necessary for document handling, other litigation support services (*e.g.*, graphic design and animation, database entry) and management services for the purpose of encoding, loading into a computer and storing and maintaining for information control and retrieval purposes, transcripts of depositions, hearing, trials, pleadings, exhibits marked by any party, briefs and accompanying

affidavits and appendices, documents produced by any party or THIRD PARTY, or a party's own attorney work product, all of which may contain CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

17. **Disclosure to Other Individuals**. Disclosure of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION may be made to individuals not identified in ¶¶ 13-14, above, as follows:

a. CONFIDENTIAL INFORMATION may be disclosed to any person not otherwise identified in ¶ 13 above as agreed by the party that designated such information CONFIDENTIAL.

b. HIGHLY CONFIDENTIAL INFORMATION may be disclosed to any person not otherwise identified in ¶ 14 above as agreed by the party that designated such information HIGHLY CONFIDENTIAL.

c. Any party may move the Court, in accordance with the procedures set forth in the Court's Rule 16 Scheduling Order for resolution of discovery disputes, for an Order that a person not identified in ¶ 13 or ¶ 14 above be given access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, respectively, after first signing an Undertaking in the form of Exhibit A attached hereto. Counsel for the moving party shall retain the original of each such signed Undertaking and must include such Undertaking with the parties' motion to the Court.

d. CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION of a producing party may also be disclosed to and/or used to examine, at deposition and at trial (or other court hearing): (i) an individual who either prepared, received or reviewed the CONFIDENTIAL INFORMATION or HIGHLY

CONFIDENTIAL INFORMATION prior to filing of this Action or previously had access or knowledge of the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, as demonstrated on the face of the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION itself or by foundation testimony elicited during a deposition or at trial; (ii) a currently employed officer, employee or expert of a producing party, and/or; (iii) a witness designated for the producing party under Federal Rule 30(b)(6) concerning any topic to which the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is relevant. This Order shall not prevent counsel from examining a witness in a good-faith effort to determine whether he or she authored or previously had access to or knowledge of CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

18. **Confidentiality of Party's Own Documents.** A party may disclose or use in any manner or for any purpose, any information or documents from that party's own files that the party itself has designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

19. **Inadvertent Disclosure**. If CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is disclosed or comes into the possession of any person not authorized to receive such information under this Protective Order, the party responsible for the disclosure shall: (a) within seven (7) days of becoming aware of such disclosure inform the designating party of all pertinent facts relating to such disclosure, including the identity of the person to whom the inadvertent disclosure was made; (b) use its best efforts to obtain the prompt return of the original and all copies of any such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION and to bind such unauthorized person or party to the terms of

this Protective Order; (c) within seven (7) days of becoming aware of such disclosure, inform such unauthorized person or party of all provisions of this Protective Order; and (d) request such unauthorized person or party to sign the Undertaking in the form attached hereto as Exhibit A. The executed Undertaking shall be served upon counsel of record for the producing party within seven (7) days of its execution by the person or party to whom CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION was disclosed. The requirements set forth in this Paragraph shall not prevent the producing party from applying to the Court for further or additional relief.

20. **Filing Under Seal**. Any information designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, if filed with the Court in connection with this Action, shall be filed under seal in accordance with the Local Rules or practice of the court in which the information is filed and shall be marked in the caption that the material is being filed under seal such as shown below:

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL PHARMACEUTICALS PLC, AVADEL US HOLDINGS, INC., AVADEL SPECIALTY PHARMACEUTICALS, LLC, AVADEL LEGACY PHARMACEUTICALS, LLC, AVADEL MANAGEMENT CORPORATION and AVADEL CNS PHARMACEUTICALS LLC, Defendants.	)	C.A. No. 21-691 (MN) **Filed Under Seal** **[Confidential / Highly Confidential] Information**

[Description of Contents]

In addition, any document that is to be filed with the Court and that contains or discloses CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall be marked "FILED UNDER SEAL" on its cover page. Material designated filed under seal shall be maintained in such manner as provided for by the Court. However, the burden of proving that such document should be sealed shall at all times remain on the party that designated the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION contained in the document.

21. **Challenging Designations**. The acceptance by any party of material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall not constitute an admission or concession, or permit an inference that such material is appropriately designated. Any receiving party may at any time request that the designating party cancel or modify the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION designation with respect to any document, object or information. Such request shall be made to counsel for the designating party in writing, and shall particularly identify the designated CONFIDENTIAL INFORMATION OR HIGHLY CONFIDENTIAL INFORMATION that the receiving party contends is not CONFIDENTIAL or HIGHLY CONFIDENTIAL, as the case may be, and the reasons supporting its contention. If the designating party does not agree to remove the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION designation within fourteen (14) days after receipt of such a request, then the party contending that such documents or material are not CONFIDENTIAL or HIGHLY CONFIDENTIAL may request by motion that the Court remove such material from the restrictions of this Protective Order, in accordance with the procedures set forth in the Court's Rule 16 Scheduling Order for resolution of discovery disputes. On such a motion, the party asserting confidentiality shall have the burden

of proving that the material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION warrants protection under this Protective Order.

22. **No Expansion of Federal Rules of Civil Procedure**. Nothing in this Protective Order shall be construed to be an implied admission or to affect or govern the scope of discovery in this Action, or to preclude any party from moving the Court for a further order pursuant to Fed. R. Civ. P. 26(c), or any other provision of the Federal Rules of Civil Procedure. Nothing contained in this Protective Order shall be construed to require production or disclosure of any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION deemed by counsel for the party possessing such material to be protected from disclosure by the attorney-client privilege or the attorney work-product immunity, or other privilege or immunity, so long as the withheld materials are identified in the manner required by the Federal Rules of Civil Procedure by the producing party. However, this Protective Order shall not prevent the parties from agreeing that certain categories of documents need not be identified, nor shall it prevent one or more parties from seeking relief from the Court if, *e.g.*, identification of individual documents would be unduly burdensome. This Protective Order shall not preclude any party from moving the Court for an order compelling production or disclosure of such material.

23. **New parties to this Action.** In the event additional parties join or are joined in this Action, they shall not have access to CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION until the newly joined party or its counsel has executed and, at the request of any party, filed with the Court its agreement to be fully bound by this Protective Order or an alternative protective order is agreed to by all parties and entered by the Court.

24. **Miscellaneous**. This Protective Order shall not be construed to prevent any of the parties, or any THIRD PARTY, from applying to the Court for relief or further or additional

protective orders, or from agreeing between or among themselves to modifications of this Protective Order, subject to the approval of the Court. The Protective Order shall not preclude the parties from enforcing their rights against any THIRD PARTY not associated with this Action who is believed to be violating their rights.

25. **Other Proceedings.** By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION pursuant to this order shall promptly notify that party of the motion in writing so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

26. **Publicly Available Information**. This Protective Order shall not apply to any information of the parties which: (a) the producing or designating party or parties agree(s) should not be designated as CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION; (b) the producing or designating party or parties agree(s), or the Court rules, is already public knowledge; (c) the producing or designating party or parties agree(s), or the Court rules, has become public knowledge other than as a result of disclosure by the receiving party, its employees or agents in violation of this Protective Order; or (d) the producing or designating party or parties agree(s), or the Court rules, has come or shall come into the receiving party's legitimate knowledge or possession independently of the producing party under conditions such that its use and/or public disclosure by the receiving party would not violate any obligation to an opposing party to this Action. The restrictions and obligations set forth herein shall not prohibit discussions

of any material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION with any person who already has or obtains legitimate possession thereof.

27. **Survival of Obligations under Protective Order**. With respect to any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, this Protective Order shall survive the final termination of this Action to the extent the information in such material is not or does not become known to the public and continues to be binding upon all persons to whom CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION is disclosed hereunder. Upon final termination of this Action, each outside litigation firm listed herein for each party may retain one copy of the case file, including pleadings or other papers filed with the Court or served in the course of the litigation, deposition transcripts, deposition exhibits, the trial record, legal memoranda, correspondence, expert reports, attorney work product, consultant and expert work product, and exhibits to any of these materials, even if such materials reflect materials designated under this Protective Order.

Within sixty (60) calendar days after final termination of this Action, including all appeals, however, all other copies and samples of material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION and any other summaries, abstracts, excerpts, indices and descriptions of such material, and information derived from such material that are recorded in any tangible form, shall be: (i) assembled and returned (except for any that may be retained by the Court) to the producing party; or, alternatively, (ii) counsel for the receiving party may certify in writing the destruction thereof. Accordingly, upon final termination of this Action, no one other than the each outside litigation firm listed herein per party shall retain any copies or samples of any material designated CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION. As to CONFIDENTIAL INFORMATION or HIGHLY

CONFIDENTIAL INFORMATION stored in computer databases or backup tapes or disks, the receiving party shall either (1) delete all such CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION, (2) restrict access to such material with passwords, or (3) designate the information CONFIDENTIAL or HIGHLY CONFIDENTIAL in a manner reasonably calculated to prevent unauthorized access to the CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION.

In the event that there are multiple parties, final termination of this Action shall be deemed to occur when the case is terminated and all appeals, or the time for such appeals, has been completed.

The Court retains jurisdiction even after the termination of the Action to enforce this Order and to make such amendments, modifications, deletions and additions to this Order as the Court may deem appropriate.

28. **Waiver or Termination of Order**. No part of the restrictions imposed by this Protective Order may be waived or terminated, except by written stipulation executed by counsel of record for each designating party, or by an Order of the Court for good cause shown. The restrictions provided for herein shall not terminate upon the conclusion of this action, but shall continue until further Order of this Court. The termination of employment of any person with access to any CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION shall not relieve such person from the obligation of maintaining the confidentiality of such information.

29. **Modification of Order; Prior Agreements**. This Protective Order may be modified, and any matter related to it may be resolved, by written stipulation of the parties without further Order of the Court. This Protective Order supersedes any agreements between the parties

regarding the confidentiality of particular information entered into before the date of this Protective Order.

30. **Section Captions.** The title captions for each section of this Protective Order are for convenience only and are not intended to affect or alter the text of the sections or the substance of the Order.

31. **Notice**. Notice under this Protective Order shall be to the parties as follows, unless this provision is modified by the parties in writing and filed with this Court: notice to Jazz Pharmaceuticals shall be made to F. Dominic Cerrito (nickcerrito@quinnemanuel.com), Quinn Emanuel Urquhart & Sullivan, LLP, 51 Madison Avenue, New York, NY 10010; notice to Avadel shall be made to Kenneth G. Schuler (kenneth.schuler@lw.com), Latham & Watkins LLP, 330 North Wabash Avenue, Suite 2800, Chicago, IL 60611 and Daralyn Durie (ddurie@durietangri.com), Durie Tangri LLP, 217 Leidesdorff Street, San Francisco, CA 94111.

32. **Order Applicable Upon Filing with the Court.** Upon filing this Protective Order with the Court, the parties agree to treat it as "So Ordered," subject to any future modifications by agreement of the parties or by the Court.

MORRIS, NICHOLAS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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August 18, 2021

It is SO ORDERED this 19th day of August 2021.

Maryellen Noreika

The Honorable Maryellen Noreika
United States District Judge

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL PHARMACEUTICALS PLC, AVADEL US HOLDINGS, INC., AVADEL SPECIALTY PHARMACEUTICALS, LLC, AVADEL LEGACY PHARMACEUTICALS, LLC, AVADEL MANAGEMENT CORPORATION and AVADEL CNS PHARMACEUTICALS LLC, Defendants.	)	C.A. No. 21-691 (MN)

UNDERTAKING OF _____

I, _____, declare under penalty of perjury that:

1. My present address is _____.
2. My present employer is _____, and the address of my present employer is _____.
3. My present occupation is _____.
4. I have received a copy of the Protective Order in this Action. I have carefully read and understand the provisions of the Protective Order. Specifically, I understand that I am obligated, under order of the Court, to hold in confidence and not disclose the contents of anything marked CONFIDENTIAL or HIGHLY CONFIDENTIAL to anyone other than the persons permitted by paragraphs 13-14 of the Protective Order. I further understand that I am not to disclose to anyone other than the persons permitted by paragraph 13 of the Protective Order any words, substances, copy, summary, abstract, excerpt, index, or description of any CONFIDENTIAL INFORMATION disclosed to me, and that I am not

to disclose to anyone other than the persons permitted by paragraph 14 of the Protective Order any words, substances, copy, summary, abstract, excerpt, index, or description of any HIGHLY CONFIDENTIAL INFORMATION disclosed to me.

5. I will comply with all provisions of the Protective Order and hereby submit to the jurisdiction of the United States District Court for the District of Delaware for the purpose of the enforcement of the Protective Order in this Action.

6. I will destroy or return all CONFIDENTIAL INFORMATION and HIGHLY CONFIDENTIAL INFORMATION that comes into my possession, and all documents and things that I have prepared relating thereto, to counsel for the party by whom I am employed or retained or from whom I received such material at the termination of this action or at any time when requested to do so. I acknowledge that return or destruction of such materials shall not relieve me from any of the continuing obligations imposed upon me by the Protective Order.

7. I understand that if I violate the provisions of the Protective Order, I will be subject to sanctions by the Court and that one or more of the parties may seek other remedies against me. I hereby submit to the jurisdiction of this Court for the purpose of enforcement of the Protective Order in this Action.

I declare under penalty of perjury of the laws of the United States (28 U.S.C. § 1746) that the foregoing is true and correct.

Dated: _____ _____

Signature

EXHIBIT PO-2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL PHARMACEUTICALS PLC, AVADEL US HOLDINGS, INC., AVADEL SPECIALTY PHARMACEUTICALS, LLC, AVADEL LEGACY PHARMACEUTICALS, LLC, AVADEL MANAGEMENT CORPORATION AND AVADEL CNS PHARMACEUTICALS, LLC. Defendants.	C.A. No. 21-691-MN
JAZZ PHARMACEUTICALS, INC. AND JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL PHARMACEUTICALS PLC, AVADEL US HOLDINGS, INC., AVADEL SPECIALTY PHARMACEUTICALS, LLC, AVADEL LEGACY PHARMACEUTICALS, LLC, AVADEL MANAGEMENT CORPORATION AND AVADEL CNS PHARMACEUTICALS, LLC. Defendants.	C.A. No. 21-1138-MN

JAZZ PHARMACEUTICALS, INC. AND JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiffs, v. AVADEL PHARMACEUTICALS PLC, AVADEL US HOLDINGS, INC., AVADEL SPECIALTY PHARMACEUTICALS, LLC, AVADEL LEGACY PHARMACEUTICALS, LLC, AVADEL MANAGEMENT CORPORATION AND AVADEL CNS PHARMACEUTICALS, LLC. Defendants.	C.A. No. 21-1594-MN

STIPULATION AND ORDER
REGARDING THE PROTECTIVE ORDER

WHEREAS, on August 19, 2021, the Court entered Protective Order (D.I. 40) in Civil Action 21-691-MN ("the First Action") ("the First Action's Protective Order");

WHEREAS, Jazz filed a second complaint against Avadel in Civil Action No. 21-1138-MN ("the Second Action"), and a third complaint against Avadel in Civil Action No. 21-1594-MN ("the Third Action"); and

WHEREAS, the First Action, Second Action, and the Third Action have been coordinated for scheduling purposes (*see* D.I. Nos. 65, 72), and will involve overlapping discovery;

IT IS HEREBY STIPULATED AND AGREED, by the parties, subject to the approval of the Court, that:

1. In light of the relatedness, coordination, and overlap of discovery in the above captioned-actions, the parties agree the First Action's Protective Order shall apply equally in the Second Action and the Third Action. Upon filing this

Stipulation the First Action's Protective Order shall be treated for all purposes as if it were entered in the Second Action and the Third Action.

2. The parties may use in the Second and Third Actions CONFIDENTIAL INFORMATION or HIGHLY CONFIDENTIAL INFORMATION produced in the First Action under the provisions of the First Action's Protective Order. This provision is not intended to limit any other cross-use of discovery between the First, Second, and Third Actions, subject to the terms of the Protective Order.
3. This stipulation does not impose affirmative discovery obligations beyond those outlined above.

Dated: December 30, 2021

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Attorneys for Defendants

SO ORDERED this 4th day of January 2022.

The Honorable Maryellen Noreika
United States District Judge

EXHIBIT PO-3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-691-MN
JAZZ PHARMACEUTICALS, INC., *et al.*, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-MN
JAZZ PHARMACEUTICALS, INC., *et al.*, Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-MN

STIPULATION AND ORDER REGARDING
PROTECTIVE ORDER MODIFICATION

WHEREAS, the above-captioned actions have been coordinated for scheduling purposes and are subject to the same protective order (see D.I. No. 42 in C.A. No. 21-691; D.I. 30 in C.A. No. 21-1138; and D.I. 17 in C.A. 21-1594);

WHEREAS, the parties have met and conferred regarding certain information Jazz designated as Confidential or Highly Confidential under the protective order, which Avadel seeks to reference in filing a new action.

NOW, THEREFORE, IT IS HEREBY STIPULATED, by the parties, and subject to the Court's approval, that:

1. The protective order in the above-captioned cases shall be modified to allow Avadel's use of materials designated as Confidential or Highly Confidential by Jazz to file and pursue one new suit in the District of Delaware based on the allegations raised in Avadel's draft counterclaims provided on March 23, 2022, and to allow Jazz's use of materials designated as Confidential or Highly Confidential by Avadel in defense of such a new suit brought by Avadel in the District of Delaware.

2. For the avoidance of doubt, Avadel and Jazz shall continue to maintain such information in a secure and safe manner and shall exercise the same standard of due and proper care with respect to the storage, custody, use, and/or dissemination of such information as is exercised by Avadel and Jazz with respect to their own respective proprietary information, including by Avadel seeking leave to file the Complaint in the new action under seal.

3. For the avoidance of doubt, by entering into this stipulation Jazz does not agree that Avadel has any valid cause of action, Jazz is solely agreeing to modifying the protective order as stated herein, and Jazz's agreement shall not limit any argument that Jazz may raise in any new action, including, without limitation, regarding any defense or claim that Jazz may raise in response to any new action brought by Avadel.

Dated: April 6, 2022

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SO ORDERED this 7th day of April 2022.

The Honorable Maryelle Noreika
United States District Judge

EXHIBIT A

CONFIDENTIAL MATERIAL OMITTED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-691-GBW [redacted]
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendants.	C.A. No. 21-1138-GBW [redacted]
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendants.	C.A. No. 21-1594-GBW [redacted]

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MEMORANDUM OPINION

August 27, 2024
Wilmington, Delaware

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

On May 12, 2021, Plaintiffs Jazz Pharmaceuticals Inc. and Jazz Pharmaceuticals Ireland Limited (collectively, "Plaintiffs" or "Jazz") sued Defendant Avadel CNS Pharmaceuticals LLC ("Defendant" or "Avadel") for patent infringement. D.I. 1. Prior to trial, Avadel stipulated that its product, Lumryz, infringed claim 24 of U.S. Patent No. 11,147,782 ("the '782 patent"). Shortly thereafter and following a one-week trial, the jury returned a verdict of no invalidity for lack of written description or enablement and no invalidity for improper inventorship.[1] Now pending before the Court is Jazz's Motion for a Permanent Injunction and for an Ongoing Royalty. D.I. 586.[2] Avadel opposes the Motion for a Permanent Injunction and contends that Jazz is not entitled to an ongoing royalty or, alternatively, is entitled to a royalty at an ongoing rate of 3.5%. D.I. 601 at 1-2. The Court held a hearing on the Motion on June 6, 2024.[3] Having reviewed the Motion and all related briefing, the Court hereby **GRANTS-IN-PART** and **DENIES-IN-PART** Jazz's Motion as follows: (1) Jazz's request for a limited permanent injunction prohibiting Avadel from seeking FDA approval and marketing Lumryz for the treatment of idiopathic hypersomnia ("IH") is **GRANTED**; (2) Jazz's request for a limited permanent injunction prohibiting the use of Lumryz for new patients in the narcolepsy market is **DENIED**; and (3) Jazz's motion for an ongoing royalty for future infringement in the narcolepsy market is **GRANTED**, pending additional briefing on the appropriate rate.

[1]Trial Tr. ("Tr.").
[2]All D.I. cites in this Opinion refer to the docket in Case No. 21-cv-00691-GBW.
[3]Permanent Injunction Hearing Transcript ("P.I. Tr.").

I. LEGAL STANDARD

"According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief." *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391, 126 S.Ct. 1837, 164 L.Ed.2d 641 (2006). Under this four-factor *eBay* test, a plaintiff must show by a preponderance of the evidence: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *Id.*

II. ANALYSIS

1. Permanent Injunction

Jazz seeks a limited permanent injunction to bar the marketing and sale of Lumryz in two markets: the narcolepsy and IH markets. D.I. 587 at 1. Jazz does not seek to enjoin Avadel from continuing to make, use, or sell Lumryz for patients who, at the time of the injunction, have already been prescribed Lumryz. *Id.* For the following reasons, the Court grants a limited injunction prohibiting Avadel from seeking FDA approval and marketing Lumryz for the treatment of IH. With respect to the market for narcolepsy, however, Jazz has not shown that it is entitled to an injunction restraining the use or sale of Lumryz for new narcolepsy patients. To compensate Jazz for Avadel's continued infringement in the narcolepsy market, the Court grants Jazz's request for ongoing royalties at a rate to be determined for any future infringing sales of Lumryz to patients with narcolepsy.

A. The *eBay* Factors Weigh Against Enjoining Lumryz for Narcolepsy Treatment.

1. *Irreparable Harm*

a. *Jazz established that it suffered some irreparable harm through past loss of market share and price erosion.*

To show irreparable harm, a patentee must prove "1) that absent an injunction, it will suffer irreparable harm, and 2) that a sufficiently strong causal nexus relates the alleged harm to the alleged infringement." *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012). Jazz contends that the prescription of Lumryz for narcolepsy has and would continue to cause Jazz irreparable injury by limiting its market share, eroding the prices of its oxybate products, and damaging its reputation as a "market leader" in narcolepsy treatment. D.I. 587 at 3-8.

The Court agrees that Avadel's infringement has caused Jazz to suffer loss of market share. *See id.* at 3-5. Indeed, there is no dispute that Lumryz competes directly with Jazz's oxybate products in the narcolepsy market, and Avadel's CEO, Gregory Divis, testified during trial that one of Avadel's "primary goals and strategies" is to target Jazz customers by educating physicians on the benefits of switching patients from Xyrem and Xywav to Lumryz. Tr. 501:1-11, 524:21-23; P.I. Tr. 13:14-23 (noting that Avadel's marketing targeted prescribers and "advocated for them to switch patients from Jazz's products to Lumryz"). Avadel's internal reporting shows that Avadel succeeded in its efforts to switch Jazz patients to Lumryz, as approximately 74% of patients on Lumryz in 2023 were "switch patients with more coming from the [Xywav] mixed salt." Tr. 523:17- 524:20; Jazz Ex. 2 at 10-12. Jazz's internal records similarly found that prescriptions for Lumryz were "coming from switched patients instead of discontinued Jazz patients." P.I. Tr. 14:4-21; Honerkamp Decl., ¶¶ 25-26.

[redacted] *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (finding irreparable injury where patentee was "forced to offer discounted rates and price concessions to third-party payors, such as health maintenance organizations, in order to keep [its product] on a favorable pricing tier, which governs what consumers pay for that drug").

Because Jazz and Avadel continue to compete directly in the narcolepsy market, the evidence that Avadel negotiated PBM agreements to [redacted] coupled with evidence that Jazz prioritized marketing campaigns aimed at switch patients "strongly suggests irreparable harm." *Natera Inc. v. ArcherDx, Inc.*, No. 20-CV-125-GBW, 2023 WL 9103876, at *3 (D. Del. 2023)(finding irreparable harm where patentee and infringer are direct competitors

and patentee has lost market share due to competition); *see also Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012) ("Direct competition in the same market is certainly one factor suggesting strongly the potential for irreparable harm without enforcement of the right to exclude."). Moreover, as Avadel recently reported that Lumryz has the potential to take 50-60% of the oxybate-treated market, there is at least some continued risk of loss of market share and price erosion if Avadel's use of Lumryz is not enjoined. *See* Tr. 525:16-527:25.

Nevertheless, Jazz's claims of irreparable harm are undermined to a degree by Jazz's public statements and filings which attribute some of Jazz's market share loss and price erosion to generic competition. Jazz admitted in recent SEC filings, for instance, that "a significant percentage of the prescriptions written for Xyrem" will be filled with generic manufacturers. Jazz Ex. 4 at 17, 36. While Jazz conceded during the Permanent Injunction Hearing that "some of the lost sales of Xyrem are coming from generic sales," Jazz failed to quantify the effects of generic sales on the market for Xyrem and maintained that its licenses to generic manufacturers would not affect demand for Xywav. P.I. Tr. 51:16-24 (arguing that does "not touch Xywav; it has nothing to do with Xywav"). Yet, in its SEC filings, Jazz recognized that generic oxybate sales "have negatively impacted and ***are expected to continue to negatively impact Xyrem and Xywav sales for patients with narcolepsy***." Jazz Ex. 4 at 17, 36 (emphasis added). In a recent 10-Q, Jazz similarly noted that "generic or AG high-sodium oxybate products or branded high-sodium oxybate entrants in narcolepsy, such as Avadel's Lumryz, have had and may continue to have the effect of changing payor or formulary coverage of Xywav or Xyrem in favor of other products, and indirectly adversely affect sales of Xywav and Xyrem." Avadel Ex. 6 at 38; *see*

also Jazz Ex. 4 ("Generic competition can decrease the net prices at which branded products, such as Xywav and Xyrem are sold.").

Given these public statements, the Court cannot disregard Jazz's generic licenses merely because they cover "unrelated patents covering Xyrem and Xywav . . . ." D.I. 610 at 4. Indeed, the Federal Circuit has explained that "'[t]he fact of the grant of previous licenses, the identity of the past licensees, the experience in the market since the licenses were granted, and the identity of the new infringer *all may affect* the district court's discretionary decision concerning whether a reasonable royalty from an infringer constitutes damages adequate to compensate for the infringement.'" *Nichia Corporation v. Everlight Americas, Inc.*, 855 F.3d 1328, 1343-44, 122 U.S.P.Q.2d (Fed. Cir. 2017) (internal citations omitted & emphasis added). The district court in *Nichia* considered that the patentee granted licenses to "'significant competitors' who posed 'major threats' to [the] flagship products." *Nichia Corp. v. Everlight Elecs. Co.*, No. 02:13-CV-702-JRG, 2016 WL 310142, at *66 (E.D. Tex. Jan. 25, 2016), *aff'd sub nom. Nichia Corp. v. Everlight Americas, Inc.*, 855 F.3d 1328 (Fed. Cir. 2017). In finding that such evidence weighed against irreparable harm, the district court noted that the licenses changed the market by making available "multiple low-priced non-infringing alternatives." *Id.* The Federal Circuit found "no clear error in the district court's finding . . . ." *Nichia*, 855 F.3d at 1344.

Similarly, here, Jazz's licenses impact the narcolepsy market by allowing generic oxybate products to enter the market and compete directly with Xyrem, Xywav, and Lumryz. Dr. Rainey, Jazz's damages expert, recognized that the licenses would create "a highly competitive environment." Rainey Tr. 67:16-23. As highlighted above, Jazz's public filings also reveal that Jazz attributed some past and future market share loss and price reduction to this generic competition. *See supra* at 5. While Jazz's licenses to generic manufacturers do not establish a

lack of irreparable harm per se,[4] these licenses undermine Jazz's effort "to lay all the blame for lost sales and price erosion on Avadel." D.I. 587 at 4. Indeed, in requesting a limited injunction, Jazz failed to distinguish or quantify the past and future market share loss and price erosion caused directly by Avadel's infringement from the harm attributable solely to generic competition. *See* D.I. 610 at 3 (maintaining that the licenses are "irrelevant"). If Jazz expects that generic manufacturers will have significant implications for its oxybate products in the narcolepsy market, as Jazz's public filings imply, this refusal to meaningfully address the impact of generic competition, at the very least, casts doubt on Jazz's claim that enjoining Lumryz would remedy most or any of the asserted future injury. *See Nichia*, 2016 WL 310142, at *66 ("[B]ecause there are multiple low-priced non-infringing alternatives from competitors available to replace the accused [] products if such products were not available, Nichia America has failed to establish the amount of any additional supposed sales, if any, in the absence of competition from Everlight. Nichia has failed to establish it will suffer irreparable harm in the absence of an injunction.").

Further, Jazz contends that, absent an injunction, Avadel's marketing strategy will cause irreparable harm to Jazz's reputation and goodwill. D.I. 587 at 7-8. Yet, Jazz's claims of reputational harm are unpersuasive for at least three reasons. First, Jazz does not practice claim 24 of the '782 patent. While the Court agrees that irreparable harm may result even where the patentee does not practice the patent-in-issue,[5] "[r]eputational harm has previously been found to weigh in favor of injunctive relief where a plaintiff was itself practicing the patented invention

[4] *Acumed*, 551 F.3d at 1328.

[5] *See Presidio*, 702 F.3d at 1363 ("Even without practicing the claimed invention, the patentee can suffer irreparable injury.").

and where there was evidence of consumer confusion, a loss of product distinctiveness, or some risk to that plaintiff's status as an innovator." *Baxalta Inc. v. Genentech, Inc.*, No. CV 17-509-TBD, 2018 WL 3742610, at *11 (D. Del. Aug. 7, 2018). Where, on the other hand, the patentee does not practice the patent-at-suit, reputational harm is unlikely because "there is no risk that consumers will be confused about the source of the various products." *Id.* Second, as Jazz seeks to enjoin the use and sale of Lumryz for patients who have never been prescribed Lumryz, the injunction "will not stop doctors and patients from associating the innovation of [Lumryz] with [Avadel]." *Id.* And an injunction may even harm Jazz's reputation "if doctors know they're trying to keep Lumryz from [new] patients who can benefit from it quite a bit." *Id.* (internal citations omitted). Finally, as to Avadel's marketing of Lumryz as the superior treatment for narcolepsy, Jazz fails to show how Avadel's marketing campaign "is causing actionable reputational harm" when Avadel's superiority claims are supported by the FDA's ODE determination. *Abbott Cardiovascular Sys., Inc. v. Edwards Lifesciences Corp.*, No. CV 19-149 (MN), 2019 WL 2521305, at *22 (D. Del. June 6, 2019).[6]

b. *There is a sufficiently strong nexus between the irreparable harm and Avadel's infringement.*

Avadel contends that Jazz fails to establish a causal nexus between its alleged irreparable harm and Avadel's infringement. D.I. 601 at 11-13. The Court disagrees. The goal of the causal nexus requirement is to ensure that there is "*some* connection" between the harm alleged and the infringing acts, and the analysis of this requirement is a "flexible" one. *Apple, Inc. v.*

[6]Jazz also fails to present any evidence that Avadel's attempts to "downplay[] the FDA's sodium finding" is likely to result in irreparable harm. "[S]imply assert[ing]" that the marketing campaign will damage Jazz's reputation is not sufficient to establish irreparable harm. *Abbott*, 2019 WL 2521305, at *22; *but see Natera*, 2023 WL 9103876, at *3 (presenting evidence that customers "started asking questions why that happened is there something wrong with Natera").

Samsung Elecs. Co., 735 F.3d 1352, 1364 (Fed. Cir. 2013) (emphasis added). A patentee can therefore satisfy the nexus requirement in a number of ways—including, for example, "with evidence that a patented feature is one of several features that cause consumers to make their purchasing decisions[,]" "evidence that the inclusion of a patented feature makes a product significantly more desirable[,]" and "evidence that the absence of a patented feature would make a product significantly less desirable." *Id.*

Avadel argues, however, that Jazz must show that Lumryz "contains no feature relevant to consumers' purchasing decisions other than what the ['782] patent claims." D.I. 601 at 12. While "a finding that the competitor's infringing features drive consumer demand for its products satisfies the causal nexus inquiry[,] . . . this rule is neither categorical nor is it mechanically applied." *Endo Pharms. Inc. v. Amneal Pharms., LLC*, No. 12 CIV. 8060 (TPG), 2016 WL 1732751, at *5 (S.D.N.Y. 2016). Indeed, in cases where evidence of customer demand for an "infringing feature" has satisfied the nexus requirement, the relevant products have been "'complex, multi-featured' products." *Janssen Prod., L.P. v. Lupin Ltd.*, 109 F. Supp. 3d 650, 700 (D.N.J. 2014), *modified on other grounds*, No. 10-5954 (WHW), 2016 WL 1029269 (D.N.J. 2016); *Genband US LLC v. Metaswitch Networks Corp.*, 861 F.3d 1378, 1384 (Fed. Cir. 2017) ("The clarified standards set forth in *Apple III* and *Apple IV* govern the causal-nexus inquiry, at least in a multi-purchaser, multi-component situation in which only a component of a larger product or system is covered by the patent in suit."). Here, however, the infringing product is a pharmaceutical with a formulation that wholly infringes claim 24, which means that Avadel could not launch Lumryz as a commercial product without Jazz's invention. Under these circumstances, it is impracticable for Jazz to treat the infringing aspects of Lumryz "as a small

component part" of the overall drug.[7] Thus, the Court will not require Jazz to identify a non-prior art "feature" to satisfy the nexus requirement. *See also Janssen*, 109 F. Supp. 3d at 700 (noting that the nexus requirement does not require the patentee to "put forth [] evidence that the claimed, non-prior art elements of the [] patent are what drive sales or consumer demand" in the case of a process patent for a pharmaceutical, given that "it is not possible to separate the process for making the finished [] product from the product itself in evaluating consumer demand and nexus").

Rather, in this matter, the nexus requirement is satisfied by the indisputable evidence of direct competition between the parties. *See Endo Pharms.*, 2016 WL 1732751, at *5 ("Competition is logically tied to injury, since directly competitive companies are most likely to be rivals for market share, sales, customers, profits, business opportunities, goodwill, and brand power."); *see also Brocade Communications Systems, Inc. v. A10 Networks, Inc.*, 2013 WL 140039, *3-*4 (N.D. Cal. 2013) (finding that patentee "has proven a sufficient nexus between the established infringement and irreparable harm from the loss of its exclusive right to practice its patents"). Indeed, the weight of the evidence reveals that Avadel intended to introduce a competing product and recognized that Lumryz would impact the market demand and the prices for Jazz's products. *See, e.g.*, Jazz Ex. 2 at 23. Thus, the Court is persuaded that there is at least "some connection" between the alleged irreparable harm and Avadel's infringement.

In sum, Jazz has presented evidence of past harm due to market share loss and the erosion of the price for Jazz's products and has shown that a sufficient nexus exists between this harm

[7] And even if Jazz could treat the infringing elements as a "feature," the formulation of a pharmaceutical is typically what drives demand. D.I. 610 at 3 (citing *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1337-40 (Fed. Cir. 2015)).

and Avadel's infringement. While "[p]ast harm to a patentee's market share[] [and] revenues" is relevant to a finding of irreparable injury,[8] here, the magnitude of Jazz's past harm—and, more importantly, the likelihood that Avadel's infringement would continue to result in such harm—is uncertain given that at least some of the harm alleged by Jazz is attributable to generic competition. Considering the clear evidence of past harm in light of Jazz's attempts to dismiss the effects of generic competition, the Court finds that this factor, at most, weighs only slightly in favor of a permanent injunction. *See Advanced Cardiovascular*, 579 F. Supp. 2d at 560 (finding no irreparable harm where "[patentee] has not addressed the fact that [a third-party competitor] holds a larger market share than [defendant]").

2. *Inadequacy of Legal Remedy*

The second *eBay* factor "is nearly indistinguishable from irreparable injury" and asks whether legal remedies are adequate to compensate the patentee for the harm caused by the infringing conduct. *Natera*, 2023 WL 9103876, at *4. Avadel contends that this factor weighs against a permanent injunction because "Jazz has willingly licensed its Xyrem and Xywav patents to ten different direct competitors, for a zero percent royalty." D.I. 601 at 15. For the reasons discussed *supra*, the Court agrees that Jazz's willingness to forego its patent rights for compensation with generic manufacturers, despite the likely impact generic sales would have on Jazz's business, "supports [a] [] conclusion that [Jazz] will not suffer irreparable harm absent an injunction." *Advanced Cardiovascular Sys., Inc. v. Medtronic Vascular, Inc.*, 579 F. Supp. 2d 554, 560 (D. Del. 2008), *dismissed*, 356 F. App'x 389 (Fed. Cir. 2009). However, Jazz's willingness to license to generic competitors "is but one factor for the [Court] to consider." *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1328 (Fed. Cir. 2008) ("[T]he amount of weight

[8] *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 861 (Fed. Cir. 2010).

given to a patentee's prior willingness to grant licenses is solely within the discretion of the district court.").

Also relevant to the Court's analysis is the evidence of at least some past market share loss and price erosion, which typically "suggests that mere damages will not compensate for a competitor's increasing share of the market." *Douglas Dynamics, LLC v. Buyers Prod. Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013); *E.I DuPont de Nemours & Co. v. Unifrax I LLC*, No. 14-1250, 2017 WL 4004419, at * 5 (D. Del. Sept. 12, 2017), *aff'd*, 921 F.3d 1060 (Fed. Cir. 2019); *Natera*, 2023 WL 9103876, at *4 (Internal citations omitted) (finding that "'loss of market share, brand recognition, and customer goodwill,' . . . demonstrate inadequacy of monetary damages"). Having considered the record before it, the Court finds that legal remedies may be inadequate to compensate Jazz for the past irreparable harm caused by Avadel's infringement. This factor therefore weighs slightly in favor of an injunction.

3. *Balance of the Equities*

"To satisfy the third *eBay* factor, the patentee must show that the balance of hardships weighs in its favor." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 645 (Fed. Cir. 2015) (citing *eBay*, 547 U.S. at 391). "This factor 'assesses the relative effect of granting or denying an injunction *on the parties*.'" *Id.* (quoting *i4i*, 598 F.3d at 862) (emphasis added). "As a preliminary matter, the balance considered is only between a plaintiff and a defendant, and thus the effect on customers and patients alleged by [the infringer] is irrelevant under this prong of the injunction test." *Acumed*, 551 F.3d at 1330. However, the Court may consider "the parties' sizes, products, and revenue sources." *i4i*, 598 F.3d at 862-63.

Here, Avadel maintains that the balance of hardship weighs against an injunction because Jazz "faces no existential risks in the absence of an injunction" while "[redacted]

[redacted]" D.I. 601 at 17. Jazz, in contrast, contends that its "resulting lost market share and being forced to compete against its own patented invention, 'places a substantial hardship' on Jazz, which 'strongly weighs in favor of an injunction.'" D.I. 587 at 11-12. Jazz adds that Avadel "cannot escape an injunction simply because it is smaller than the patentee or because its primary product is an infringing one." *Id.* at 13 (citing *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1156 (Fed. Cir. 2011)). According to Jazz, Avadel's claims that an injunction would destroy its business are particularly inconsequential, considering the Federal Circuit's resolve that "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Windsurfing Intern'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 n. 12 (Fed. Cir. 1986).

Yet, this is not a case where an infringer *elected* to build its business around an infringing product. *See Hynix Semiconductor Inc. v. Rambus Inc.*, 609 F. Supp. 2d 951, 970 (N.D. Cal. 2009) (distinguishing *Windsurfing* where the record proves that the infringement was not willful). Rather, Avadel's investment into Lumryz began in 2019, at a time when "claim 24 of the '782 patent ***did not exist***." D.I. 601 at 17 (emphasis in original); P.I. Tr. 83:20-84:7. While Jazz contends that Avadel "made a 'choice' to focus exclusively on Lumryz," this too was a decision made by Avadel in 2019, and Avadel maintains that it was wholly unaware of Jazz's intent to patent a similar treatment when the decision to prioritize Lumryz was made. Tr. 548:12-13. According to Avadel, when the'782 patent issued in October 2021, Avadel continued to have no knowledge of the patent, but "the design of Lumryz was locked in . . . [and] fully ready for FDA approval." D.I. 601 at 17. Thus, Avadel's alleged harm was not, as Jazz contends, "self-inflicted." D.I. 587 at 1. And "the potential destruction of [] [Avadel's] business

should carry some weight in the balancing of harms under the four-factor test reaffirmed in *eBay*." *See Hynix*, 609 F. Supp. 2d at 970; *see also Wonderland Switzerland AG v. Evenflo Co., Inc.*, No. 1:20-CV-00727-JPM, 2023 WL 4098571, at *7 (D. Del. June 7, 2023) ("[C]ourts may still consider hardships suffered by an infringer when determining whether an injunction is warranted.").

Considering the harm of an injunction to Avadel against the harm to Jazz of allowing Avadel's continued infringement, the Court finds that the balance tilts in Avadel's favor. Avadel is "a much smaller company" that "depends entirely on the sales of the enjoined products for its revenue." *Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1379 (Fed. Cir. 2020); *but see Commonwealth Sci. & Indus. Rsch. Organisation v. Buffalo Tech. Inc.*, 492 F. Supp. 2d 600, 606 (E.D. Tex. 2007) (finding that hardship of injunction was not catastrophic where the infringing products made up "only eleven percent of [the infringer's] business"). Thus, even the limited injunction sought by Jazz could "[redacted]" Divis Decl., ¶ 6. And while Jazz will undoubtedly suffer harm from having to compete directly against an infringing product, "[Lumryz] is not a copycat product[] but was independently developed and provides important advantages over [Jazz's products] for patients." *Conceptus, Inc. v. Hologic, Inc.*, No. C 09-02280 WHA, 2012 WL 44064, at *3 (N.D. Cal. Jan. 9, 2012). Given this evidence and [redacted],[9] the Court finds that the balance of the equities weighs against an injunction.[10] *Id.* (finding that the

[9]D.I. 601 (explaining that, if an injunction is granted, "[redacted]").

[10]Jazz argues that the balance of the equities should not favor Avadel because "Avadel has purported to have invented other unit dosage forms that would *not* infringe Jazz's claim 24." D.I. 587 at 11. Jazz concedes, however, that "Avadel did not present any evidence of a non-infringing alternative to claim 24 at trial," and Jazz relies on disclosures in Avadel's patent that the "first principal structural embodiment" of Avadel's formulation does not include a viscosity

balance of hardships weighed against an injunction where the infringer "would have to lay off nearly three hundred employees who are directly related to the manufacture and research of [the infringing product] if an injunction is imposed").

4. *Public Interest*

More than any other *eBay* factor, the public interest strongly favors denying Jazz's request to enjoin Lumryz for narcolepsy. "The heart of the patent grant is the right to exclude. *See* 35 U.S.C. § 154(a)(1) ("Every patent shall contain ... a grant to the patentee ... of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States."). "Typically, in a patent infringement case, although there exists a public interest in protecting rights secured by valid patents, the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of [injunctive] relief." *Hybritech Inc. v. Abbot Laboratories*, 849 F.3d 1446, 1458 (Fed.Cir.1998); *Wesley Jessen Corp. v. Bausch & Lomb, Inc.*, 209 F. Supp. 2d 348, 404 (D. Del. 2002), *aff'd*, 56 F. App'x 503 (Fed. Cir. 2003) ("In patent cases, courts only exercise their discretion to deny injunctive relief when the harm to the public from granting the injunction is so severe that it outweighs the patentee's individual right to exclude."); *Amgen, Inc. v. Sanofi*, 872 F.3d 1367, 1381 (Fed. Cir. 2017) (holding that where a "plaintiff fails to show 'that the public interest would not be disserved by a permanent injunction,' then the district court may not issue an injunction"). Particularly, "[i]n litigation such as this involving a medical product, the public

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enhancing agent or an acid. *Id.* (noting that Avadel's witness confirmed during trial that "everything in [the '062 Patent] to be true and accurate."). This evidence, however, does not persuade the Court that Avadel had a "new design around [that] was ready for implementation" and does not defeat Avadel's claim that the balance of the harm weighs in its favor. *See Douglas*, 717 F.3d at1345 ("If indeed [defendant] had a non-infringing alternative *which it could easily deliver to the market*, then the balance of hardships would suggest that Buyers should halt infringement and pursue a lawful course of market conduct." (emphasis added)).

has 'two primary interests'—i.e., the 'protection of intellectual-property rights and access to necessary and effective medical care.'" *Abbott*, 2019 WL 2521305, at *25 (quoting *Baxalta*, 2018 WL 3742610, at *12). Thus, courts have denied motions for injunctions "when doing so would eliminate 'an important alternative for patients.'" *Id.* (quoting citation omitted); *see also Custom Designs of Nashville, Inc. v. Alsa Corp.*, 727 F. Supp. 2d 719, 727 (M.D. Tenn. 2010) ("A number of cases indicate that the denial of an injunction for reasons of public interest is limited to cases where public health or safety are threatened, but that in general, the benefits derived from protecting a person's patent sufficiently serve the public interest.").

Avadel contends that a permanent injunction would harm the public interest by removing from the market a treatment for narcolepsy that offers "unique medical benefits" otherwise not offered by Xyrem and Xywav. D.I. 601 at 3. Specifically, Avadel argues that Lumryz constitutes an important alternative for patients with narcolepsy by offering those patients the only single-dose treatment regimen in the market. *Id.* at 4. Xyrem and Xywav, on the other hand, require patients with narcolepsy "to take one dose of oxybate at bedtime and a second dose two and a half to four hours later." Tr. 635:14-22. Avadel's expert, Dr. Corser, testified during trial that Xyrem and Xywav "ha[ve] not been appealing, either for doctors or for patients" because the twice-nightly treatment regimen means that patients must wake up to take the second dose. *Id.* at 635:14-22. Conversely, because Lumryz is only taken once before bedtime, Lumryz "giv[es] narcolepsy patients—for the first time—the chance to get an undisturbed night's sleep." D.I. 601 at 3.

To counter Avadel's argument that Lumryz is the superior treatment, Jazz cites "data show[ing] that both parties' products similarly reduce the number of narcolepsy nighttime awakenings from about 80 to about 40." D.I. 610 at 1; Jazz Exs. 20-22. Yet the data cited by

Jazz does not refute Avadel's claim that Lumryz gives patients with narcolepsy "a better chance to get undisturbed sleep than Jazz's products," as the basis for Avadel's claim is not that Lumryz is more *effective* in *treating* or *preventing* symptoms of narcolepsy. Rather, Avadel argues that, unlike Xywav and Xyrem, Lumryz offers a unique benefit to patients *by eliminating the requirement* that patients take a second late-night dose. D.I. 601 at 4. Accordingly, Avadel claims that an injunction would harm the public interest by preventing patients with narcolepsy from accessing a treatment that is easier to administer. Stern Decl., ¶¶ 6-8

Notably, the FDA similarly found that Lumryz 's single dose regimen treatment made it clinically superior "to every previously approved oxybate drug . . . , [including] both Xywav and Xyrem," for patients with narcolepsy. Avadel Ex. 1 at JTX-112.3. The FDA's determination relied on the opinions of "agency sleep experts" who agreed that "disrupting sleep contributes to chronic sleep loss[] [and] is well known to cause reduced performance, increased risk for accidents and death, and detrimental effects on both psychological and physical health." *Id.* at JTX-0112.3, JTX-112.33. Thus, the FDA found that a treatment for narcolepsy that required patients "to wake up to take a second dose" would be "antithetical to [the treatment's] goal of improving sleep" because it would force a nocturnal arousal on patients who already struggle to get sufficient night-time sleep. *Id.* at JTX-112.29. Because Lumryz eliminated the need for patients with narcolepsy to wake up for the second dose, the FDA concluded that Lumryz was "inherently more convenient, easier, and less burdensome," and thus was the superior treatment for narcolepsy.[11] *Id.* at JTX-112.30.

[11]Jazz contends that "[t]he FDA found that Xywav's significantly lower amount of sodium is 'safer' for 'all patients with narcolepsy.'" D.I. 587 at 9. Jazz, however, mischaracterizes the FDA's findings, which were "not based on Lumryz providing greater safety than Xyrem and Xywav" and did "not respond[] to each safety argument from Jazz." Avadel Ex. 1 at JTX-

Jazz contends that "the FDA made clear that its finding was not based on better safety or efficacy." D.I. 587 at 15. While the Court agrees that the FDA did not determine whether Lumryz was a safer or more effective treatment for narcolepsy, Avadel can show that its infringing product constitutes an important alternative for patients even in the absence of such evidence. *Baxalta* is illustrative. 2018 WL 3742610. There, the district court found that a Breakthrough Therapy designation by the FDA "indicate[d] that the [infringing] drug may demonstrate a substantial improvement over existing therapies" where the patentee sought to enjoin the sale and production of an infringing drug used to treat hemophilia. *Id.* at *3. In denying injunctive relief, the *Baxalta* court noted that the infringing drug was administered through "a once-weekly subcutaneous injection" while the patented treatment required administration by infusion "at least two times a week." *Id.* Identifying this difference in the administration requirements of each treatment, the *Baxalta* court held that the infringing product "represent[ed] a potential sea change in the treatment of [] hemophilia" because it offered patients an option for "prophylactic therapy with *a significantly lower treatment burden*." *Id.* at

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0112.34. Acknowledging "that the sodium content of Lumryz raises [] [some] safety concern[s]," particularly for patients with sensitivity to sodium, the FDA determined that, with respect to both patients with sodium restrictions and patients who are not sensitive to sodium, "the benefit offered by once-nightly dosing would [still] outweigh the risk of increased sodium intake." *Id.* at JTX-0112.33; *id.* at JTX-0112.34 (noting that the FDA "acknowledged [] that Lumryz has a higher sodium content than Xywav and addressed why Lumryz is still clinically superior to Xywav"). Thus, the Court does not read the FDA's superiority determination as applying only to patients with no salt-sensitivity. *Compare* D.I. 587 at 16 (claiming that the FDA's "clinical superiority finding was not for 'the entire patient population for which [Lumryz] is intended'") *with* Avadel Ex. 1 at JTX-0112.32 ("[W]e believe that the benefit of Lumryz's once-nightly dosing outweighs the safety concern raised by its increased sodium content for a substantial number of narcolepsy patients.") *and* Avadel Ex. 1 at JTX-0112.33 ("For certain sodium-sensitive patients with narcolepsy, the benefit offered by once-nightly dosing would outweigh the risk of increased sodium intake . . . .").

*13 (emphasis added). Thus, "the public interest favor[ed] availability of [this less burdensome] treatment." *Id.*

Similarly, in this matter, the FDA's superiority determination strongly indicates that the public interest favors the availability of Lumryz for narcolepsy. As with the infringing treatment in *Baxalta*, Lumryz's single-dose treatment regimen benefits patients with narcolepsy by eliminating the need to "wak[e] up to take medication during the night after falling asleep[]." Avadel Ex. 1 at JTX-0112.12. The FDA explained that this benefit can be crucial for patients with narcolepsy, since "even [] a single nocturnal arousal[] [] can [cause] impairment of alertness and decline in cognitive performance the following day." *See id.* at JTX-01112.29 ("Awakening to take a second dose necessarily disrupts sleep and causes fragmented sleep. A person with disrupted sleep cannot simply return to sleep and resume their normal sleep cycle. . . . So, upon taking a second dose of Xyrem or Xywav, after the minimum of 5-15 minutes to return to sleep, such sleep does not resume where the patient left off to take their medication."). A single-dose treatment regimen, on the other hand, aligns more effectively with the goal of narcolepsy treatment (i.e., "maximize the time in sleep and minimize wake time") by eliminating the need to wake mid-sleep for a second dose. *Id.* Such a treatment also reduces the burden on patients of having to arrange for such a late-night dose. *Id.*; Stern Decl., ¶¶ 7-8 (noting "[t]hat patients taking Xyrem or Xywav must set an alarm to take the second dose in the middle of the night" makes compliance less likely, as "patients [] struggle[] to adhere to the dosing regimen"); Lavender Decl., ¶ 12 ("[I]t is not some minor issue that people do not want to have to set an alarm in the middle of the night. Neither Xyrem nor Xywav is an easy treatment. The treatment upends your life."). Thus, Avadel has proven that Lumryz represents a "sea change" in the treatment of narcolepsy by offering patients a less burdensome treatment option.

In light of this evidence, the public interest weighs notably against even the "limited" injunction sought by Jazz. Lumryz is the only single-dose treatment for narcolepsy, and the FDA's superiority determination recognized that Lumryz is "significantly more convenient for patients" and "an advancement in the ease of drug administration." Avadel Ex. 1 at JTX-01112.29. Avadel offered first-hand accounts from patients and providers noting their preference for Lumryz's once-nightly treatment regimen over Jazz's two-dose oxybate treatments. *See, e.g.*, Lavender Decl., ¶¶ 12-17; Patient 1 Decl., ¶¶ 6-11; Patient 2 Decl., ¶¶ 6-10. While Jazz contends that a limited injunction reduces the likelihood of public harm by ensuring that no existing Lumryz patients are enjoined from continuing their use of Lumryz, Jazz seeks an injunction that "would make Lumryz unavailable 'to the vast majority of [narcolepsy] patients in need of [Lumryz] treatment.'" D.I. 601 at 10 (citing *Baxalta*, 2018 WL 3742610, at *13). In doing so, Jazz ignores that patients with narcolepsy who have not been prescribed Lumryz would also "continue to benefit[] from having a choice of products."[12] *Conceptus*, 2012 WL 44064, at *3-*4; *see also Baxalta*, 2018 WL 3742610, at *12 (explaining that the public interest disfavored enjoining a treatment that "differ[s] in meaningful ways" from other existing products on the market). In fact, there are "multiple reasons patients may want to take Lumryz in the future but are not taking it yet." Stern Decl., ¶ 21. As Avadel's expert Dr. Thomas Stern explained:

[12]The Court recognizes that some patients may benefit more from Xywav given its reduced sodium content. However, the FDA found "that the benefit of Lumryz's one-nightly dosing outweighs the safety concern raised by its increased sodium content for a substantial number of narcolepsy market." Avadel Ex. 1 at JTX-0112.32. While Jazz disagrees and notes that has initiated proceedings to challenge the FDA's determination on this ground, the public interest that the Court seeks to protect is the interest in patient choice, and the Court's decision ensures that all patients seeking narcolepsy treatment have the option to take a treatment that offers unique and substantial benefits. The law does not require the Court to find that Lumryz *is* the best treatment option for all patients with narcolepsy.

> Some [patients] have not yet been diagnosed with narcolepsy. Others have been diagnosed with narcolepsy and would benefit from Lumryz but have not started taking it because they have not had a follow-up visit recently or have not yet gone through the somewhat cumbersome process of enrolling in the FDA-mandated risk evaluation and mitigation system (REMS) for Lumryz or securing coverage from their health insurer. Some are not yet 18 years of age. *Id.*

Jazz responds that these patients can be treated with Jazz's oxybate products. *See* D.I. 597 at 14 (citing JTX87.3) (noting "that Lumryz's labeling instructs that Jazz's patients are to switch to 'the nearest equivalent [Lumryz] dosage in grams per night.'"). Yet, Jazz does not offer a once-nightly treatment for narcolepsy, and the record does not indicate that Jazz intends to offer a once-nightly narcolepsy treatment "for commercial sale very soon." *Edwards Lifesciences AG v. CoreValve, Inc.*, No. CV 08-91 (GMS), 2014 WL 1493187 (D. Del. Apr. 15, 2014) (excluding from an injunction those patients who "cannot be helped" by the patentee's products). Thus, with respect to their administration requirements, Jazz's oxybate treatments and Lumryz "are 'not interchangeable products." *Abbott*, 2019 WL 2521305, at *27 (internal citations omitted). Given the detrimental effects of sleep deprivation and sleep fragmentation for patients with narcolepsy, it is in the public's interest to have continued access to the less burdensome treatment. Avadel Ex. 1 at JTX-01112.13. Moreover, this interest in protecting patient access to the only once-nightly narcolepsy treatment in the narcolepsy market "'militates strongly against an injunction.'" *Abbott*, 2019 WL 2521305, at *26-*27 (internal citations omitted); *Conceptus*, 2012 WL 44064, at *4 (N.D. Cal. Jan. 9, 2012).

In sum, having considered each of the *eBay* factors, the Court finds the threat to Avadel's business and, more importantly, the substantial harm to the public interest that would result from an injunction outweigh any irreparable injury suffered by Jazz in the absence of such injunctive relief. Accordingly, Jazz's request for a permanent injunction barring the prescription of Lumryz for the treatment of narcolepsy is **DENIED**.

B. *The eBay factors weigh in favor of enjoining Avadel from seeking FDA approval and marketing Lumryz for IH.*

1. *Irreparable Harm*

According to Jazz, Lumryz's entrance into the market for IH would irreversibly harm Jazz's market share and damage its ability to build its reputation as the exclusive market leader. D.I. 587 at 4-5, 7-8. For the following reasons, the Court agrees that Jazz would suffer irreparable injury if Avadel is not enjoined from seeking FDA approval and marketing Lumryz for IH.

Unlike the narcolepsy market where Jazz's products compete with several other oxybate therapies, Jazz's Xywav is the only FDA-approved treatment for IH. Tr. 92:17-21, 520:5-8. While Avadel does not currently manufacture or sell competing products in the IH market, Avadel does not dispute that it is pursuing FDA approval of Lumryz for the treatment of IH. Tr. 519:17-19. The evidence shows that Avadel's interest in the IH market stems from its recognition that the market holds "a lot of opportunity" because "there's a robust patient population . . . with only one currently FDA approved treatment, [Xywav]." Jazz Ex. 2 at 23. Because Xywav is the only FDA approved treatment for IH, Lumryz's entrance into the IH market would undoubtedly cause Jazz to suffer significant injury.

Indeed, with FDA approval, Lumryz will compete head-to-head against Xywav in a newly-developing market. *Douglas,* 717 F.3d at 1345 ("Where two companies are in competition against one another, the patentee suffers the harm—often irreparable—of being forced to compete against products that incorporate and infringe its own patented inventions."). Avadel responds that Jazz's complaints about "losing its first-mover advantage are overstated." D.I. 601 at 4 (internal citations omitted). Yet, evidence shows that, since acquiring FDA approval to market Xywav for IH in August 2021, Jazz has seen dramatic increases in the

number of IH patients taking Xywav year-to-year. P.I. Tr. 16:7-10, 17:12-19 (noting a 59% growth of Xywav for IH in 2023). Additionally, as recently as March 2024, Avadel's CEO admitted that Avadel "watched [Xywav] advance" over the two years since their launch in the IH market and noted "a lot of opportunity remained" because Jazz showed less than a ten percent market penetration. Jazz Ex. 2 at 23:10-21.

Given this evidence, the Court agrees that an encroachment by Avadel at such a "crucial inflection point" in the development of the IH market would harm Jazz by allowing Avadel to "capture and define the market with pirated technology." *Illumina, Inc. v. Qiagen, N.V.*, 207 F. Supp. 3d 1081, 1093 (N.D. Cal. 2016). "[A]s the first entrant into the marketplace, [Avadel] would have advantages that include working with the best facilities and potential customers and being perceived as an innovator in the field." *See Butamax Advanced Biofuels LLC v. Gevo, Inc.*, 868 F. Supp. 2d 359, 375 (D. Del.), *remanded-in-part on other grounds. Butamax(TM) Advanced Biofuels LLC v. Gevo, Inc.*, 486 F. App'x 883 (Fed. Cir. 2012); *see also Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (finding irreparable harm where "price erosion and loss of market position was likely").

Moreover, Xywav's title as the only FDA-approved treatment for IH "is an intangible asset that is part of a company's reputation . . . ." *Douglas*, 717 F.3d at 1345. Because Jazz intends to use its exclusivity in the IH market to brand itself as the market leader, Avadel's entrance into the market would strip Jazz of a unique selling point critical to growing its reputation and goodwill. *See id.* at 1344 (recognizing that a patented product may "lose some of its distinctiveness and market lure because competitors could contend that they had 'similar features' without noting that those features infringe"). Thus, Jazz would also suffer reputational harm from "being precluded from marketing to potential and existing customers that it is the

exclusive market leader." *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930-31 (Fed. Cir. 2012). This reputational harm and the accompanying market share loss caused by Avadel's direct competition would likely be irreparable. *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc.*, 821 F. Supp. 2d 681, 694 (D.N.J. 2011), *aff'd and remanded sub nom. Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc., USA*, 748 F.3d 1354 (Fed. Cir. 2014) (finding irreparable harm where "[p]laintiffs and [d]efendants are two head -to-head competitors in the [relevant] marketplace; every sale of [d]efendants' generic [product] is a lost sale by Plaintiff"). Accordingly, this factor weighs in favor of a permanent injunction.[13]

2. *Inadequacy of Legal Remedies*

Additionally, Jazz has satisfied its burden of showing that monetary remedies would not adequately compensate the harm caused by Lumryz's introduction into the market for IH. This factor can be met by evidence of "loss of market share, brand recognition, and customer goodwill . . . particularly when the infringing acts significantly change the relevant market." *i4i*, 598 F.3d at 862. Here, the approval of Lumryz for IH would significantly change the market by allowing a second treatment to compete directly with Jazz's Xywav. *See Novozymes A/S v. Genencor Int'l, Inc.*, 474 F. Supp. 2d 592, 613 (D. Del. 2007) (finding legal remedies inadequate because patentee and infringer "are head-to-head competitors, and [patentee] has a right, granted by Congress, not to assist its rival with the use of proprietary technology"). Also, as the Court noted *supra*, Jazz's exclusivity in the IH market is itself an intangible asset, and Jazz will likely suffer reputational harm that cannot be compensated by legal remedies. *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1340 (Fed. Cir. 2012) ("Loss of business

[13]For the same reasons noted with respect to Jazz's request to enjoin Lumryz for narcolepsy, Jazz has shown a sufficient nexus between the irreparable harm asserted by Jazz and Avadel's continued infringement. *See supra* at 8-10.

opportunity or damage to brand recognition could provide a basis for concluding that monetary relief would be inadequate.").

3. *Balance of the Equities*

The balance of the equities also tips in Jazz's favor. While the Court is persuaded that enjoining Lumryz for narcolepsy would irrevocably harm Avadel's business, Avadel cannot allege the same injury with respect to the IH market, where Avadel still lacks FDA approval to sell Lumryz. And while Avadel notes that it "intends to invest $30-40 million" in clinical trials evaluating the contributions of Lumryz in treating IH, Avadel concedes that it "has not yet started [any] clinical trial[s]" and would not do so if an injunction was granted. *See* P.I. Tr. 64:15-21, 86:1-8 (explaining that the trials would not occur "if there was no way that it could sell the product at the conclusion of that clinical trial."). Thus, enjoining Lumryz for IH would not spell "the end of Avadel." *See* D.I. 601 at 17.

"On the other hand, requiring [Jazz] to compete against its own patented invention . . . places a substantial hardship on [Jazz]," particularly given that Lumryz would be the only other FDA-approved treatment for IH. *Robert Bosch*, 659 F.3d at 1156; *see also* Jazz Ex. 2 at 23 (Avadel's CEO recognizing "a lot of opportunity" in the IH market). Jazz contends that it is working to grow its position and reputation in the IH market and, as the Court noted above, Jazz has a pointed interest in protecting its market exclusivity. This factor therefore weighs in favor of a permanent injunction.

4. *Public Interest*

Avadel contends that the same public interest considerations that counsel against enjoining Lumryz for narcolepsy are relevant to Jazz's request to enjoin Lumryz for IH. D.I. 601

at 9-10. For the following reasons, the Court disagrees and finds that the public interest weighs in favor of enjoining Lumryz in the IH market.

According to Avadel, "IH is best thought of as being on a spectrum with narcolepsy," as "[p]atients with either condition suffer from excessive daytime sleepiness," "[d]iagnostic criteria are similar and imprecise," and "oxybate is a very effective treatment for IH." *Id.* at 9. While the Court agrees that both narcolepsy and IH are sleep-related disorders that share many common symptoms, the weight of the evidence indicates that the conditions are distinguishable. Jazz's expert witness, Dr. Richard K. Bogan, explained that "Narcolepsy and IH are two unique chronic sleep disorders with the common symptom of excessive daytime sleepiness ('EDS')." Bogan Decl., ¶ 10. While both conditions cause patients to suffer EDS, "IH patients[] [] present other symptoms that are typically distinct from narcolepsy." *Id.*, ¶ 14. These symptoms include "sleep inertia where the patient experiences difficulty waking from a long sleep, unrefreshing naps, and long sleep times of 11 or more hours per 24-hour period." *Id.*

Avadel's expert, on the other hand, alleged that IH was particularly similar in "presentation and diagnostic criteria to [Narcolepsy Type 2]," making the two conditions "difficult to distinguish." Stern Decl., ¶ 14. While Dr. Bogan agreed that IH and narcolepsy Type 2 have many "overlapping symptoms," he explained that Type 2 tends to cause patients to suffer from fragmented sleep. Bogan Decl., ¶ 12. Patients with IH, on the other hand, "typically have longer sleep times." *Id.* Thus, Dr. Bogan testified that practitioners can distinguish between the two conditions. *Id.* Dr. Bogan supported his opinions with several peer-review papers "consistently characterize[ing] IH and narcolepsy [] as distinct diseases." *Id.* at Ex. C, Dauvilliers 2022 at 7 (explaining that IH "may coexist with other disorders. . . but is incompatible with others, such as narcolepsy"); Ex. D, Landzberg, D and Trotti, L.M., *Is*

Idiopathic Hypersomnia a Circadian Rhythm Disorder?, Curr. Sleep. Med. Rep. 5(4):201-206 (2019) ("IH is diagnosed based on clinical history in combination with objective quantification of excessive daytime somnolence . . . after excluding other causes of sleepiness such as narcolepsy type 1 [and] narcolepsy type 2"). Several of these papers distinguished IH "from narcolepsy on the basis of the presence of prolonged rather than short diurnal sleep periods . . . ." *Id.* at Ex. E, Bruck, D. and Parkes, J.D., *A comparison of idiopathic hypersomnia and narcolepsy-cataplexy using self report measures and sleep diary data*, JNNP 60:576-578 (1996); Ex. F, Manfredi, R.L., et al., *Disorders of excessive sleepiness: narcolepsy and hypersomnia*, Semin. Neurol. 7(3):250-58 (1987) ("Nocturnal sleep is typically disrupted in narcolepsy, whereas in idiopathic hypersomnia it is prolonged."). During a conference presentation in March 2024, Avadel's CEO similarly recognized that IH is "different from narcolepsy in that [IH patients] really physically struggle at times with waking up with the deep sleep inertia that they suffer from." Jazz Ex. 2 at 23:10-24:1.

The separate FDA-labeled-indications for IH and narcolepsy also support the Court's finding that the two conditions are distinct. For instance, Xywav is FDA-approved for once nightly administration to treat IH and must be administered in two doses to treat narcolepsy. Citing only to the declaration of its expert, Dr. Stern, however, Avadel argues that the Court should disregard the FDA's approval of once nightly Xywav to treat IH because a "vast majority of IH patients take [Xywav] twice nightly." D.I. 601 at 8 (citing Stern Decl., ¶ 16). Yet, Avadel provided no evidence to substantiate Dr. Stern's claim. *See* Stern Decl., ¶ 16 (noting only that, "in [his] own practice, [Dr. Stern] always starts patients on twice-nightly oxybate for IH"). Jazz, on the other hand, cited clinical research finding no substantial difference between once nightly dosing and twice nightly dosing of Xywav for IH treatment. *See* Jazz Ex. 26 at 63. When

viewed as a whole, the weight of the evidence shows that IH and narcolepsy are distinct conditions and that Xywav can—and very likely is—administered in a single dose to treat the symptoms of IH.

Given these distinctions between the two conditions, Avadel cannot rely on the FDA's determination that "Lumryz is clinically superior to Xywav" to support its claim that the public interest weighs against the injunction of Lumryz for IH. Indeed, the FDA's superiority determination extends only to the narcolepsy market. Avadel responds that the Court's decision to enjoin Lumryz for IH should not turn on its lack of FDA approval because "[t]he key public-interest consideration is whether an injunction would cut off patient access to a differentiated product that offers a 'unique' medical benefit, not whether there has been a clinical superiority determination." D.I. 601 at 9. While the Court agrees that the public interest may disfavor an injunction even in the absence of an FDA superiority finding, in this case, the FDA's ODE determination was crucial to the Court's finding that Lumryz offered a "unique" medical benefit to patients with narcolepsy. *See supra* at 15-21. In opposing an injunction of Lumryz™ for narcolepsy, Avadel argued consistently with the FDA that Lumryz was the superior treatment because it eliminated the need for narcolepsy patients to wake for a late-night second dose. *See* D.I. 609 at 4-5. After reviewing the FDA's ODE determination and the evidence before it, the Court agreed that the public had a significant interest in accessing the only single-dose treatment for narcolepsy. *See supra* at 15-21. Given the FDA's approval of once-nightly Xywav as a safe and effective treatment for IH, however, the Court is not persuaded that Lumryz offers IH patients the same "unique" benefit. As Avadel has not shown that Lumryz offers any other distinct benefits to patients with IH, the Court cannot find that enjoining Lumryz for IH would harm the public interest by "cutting off" access to a differentiated product.

Ultimately, to show that the public interest weighed against an injunction, Avadel had the burden to prove that enjoining Lumryz for IH would result in a harm to the public that outweighs the public's competing interest in incentivizing "innovative drug companies to continue costly development efforts." *Sanofi-Synthelabo*, 470 F.3d at 1383 (finding that the "'public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents' tips the scale in [the patentee's] favor"). Yet, Avadel failed to show that Lumryz is a superior or unique treatment for IH. Avadel's claim that "[p]hysicians have [] urged Avadel to seek FDA approval for Lumryz in IH" is similarly insufficient to outweigh the public's interest in enforcing patent rights and encouraging innovation. *See* D.I. 601 at 8. Accordingly, this factor weighs in favor of enjoining Lumryz for IH.

5. *Unclean Hands*

Avadel contends that Jazz cannot obtain equitable relief because of Jazz's attempts to use "unlawful and improper means" to block Avadel's participation in the marketplace. D.I. 601 at 18. Federal Rule of Civil Procedure 8(c), however, requires the affirmative defense of unclean hands to be pled affirmatively, and "[f]ailure to raise an affirmative defense by responsive pleading or by appropriate motion generally results in the waiver of that defense." *Charpentier v. Godsil*, 937 F.2d 859, 863 (3d Cir.1991). Because Avadel failed to plead unclean hands, that defense is waived. D.I. 610 at 5. Moreover, the defense would not succeed even if properly pled by Avadel given that "the primary principle guiding application of the unclean hands doctrine is that the alleged inequitable conduct must be connected, *i.e.,* have a relationship, to the matters before the court for resolution." *In Re New Valley Corp.,* 181 F.3d 517, 525 (3d Cir.1999) (internal citations omitted). "In the context of patent litigation, assertions of unclean hands have typically succeeded only in situations in which the misconduct related in some way to the

procurement of the particular patent in question." *In re Gabapentin Pat. Litig.*, 648 F. Supp. 2d 641, 650 (D.N.J. 2009). Jazz's exclusion of Avadel from the marketplace does not directly relate to Jazz's claim asserting its patent rights. Accordingly, the defense, even if properly pled, would not bar Jazz from seeking an injunction.

Because the *eBay* factors counsel in favor of an injunction, Jazz's request to enjoin Avadel from pursuing FDA approval for Lumryz to treat IH and from marketing Lumryz for IH treatment is **GRANTED**.

2. Ongoing Royalties

A. *Jazz is entitled to ongoing royalties for sales of Lumryz for narcolepsy.*

"If the court determines that a conduct-barring injunction is not warranted, it may instruct the parties to try to negotiate an ongoing royalty and, if the parties cannot agree, award a royalty." *Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1377 (Fed. Cir. 2017). While the jury awarded Jazz a 3.5% royalty rate for past damages, Jazz argues that the awarded royalty should be increased to an ongoing rate of "27% through 2025, 13% from 2026 through 2032, and 3.5% from 2033 through February 2036." D.I. 587 at 17-18. Avadel, on the other hand, requests that the Court "view the jury award as a fully-paid-up royalty" or, alternatively, "treat the award as a determination that Avadel should pay a 3.5% royalty on 20% of Avadel sales." D.I. 601 at 19.

Although the Court recognizes that the award of an ongoing royalty is not automatic, the Court agrees with Jazz that an award of royalties is warranted to remedy the future sales of Lumryz for narcolepsy. The decision to award such a royalty is solely within the Court's discretion. *See Paice LLC v. Toyota Motor Corp.,* 504 F.3d 1293, 1315 (Fed.Cir.2007). Moreover, "the Federal Circuit has indicated that a prevailing patentee should receive

compensation for any continuing infringement." *Apple, Inc. v. Samsung Elecs. Co.*, No. 12-00630-LHK, 2014 WL 6687122, at *7 (N.D. Cal. Nov. 25, 2014) (citing *Telcordia Techs., Inc. v. Cisco Sys., Inc.*, 612 F.3d 1365, 1379 (Fed.Cir.2010)). Here, the record clearly establishes that Avadel intends to offer and sell a wholly infringing product to treat narcolepsy. The evidence also shows that Avadel recognizes that its product will compete directly with Jazz's oxybate products for market share and other market opportunities. As some evidence indicates that Avadel has and continues to target patients currently being treated by Xyrem or Xywav (i.e., so-called "switch-patients"), the Court agrees that an ongoing royalty award is necessary to compensate for Avadel's continuing infringement of the '782 patent. Avadel's motion for ongoing royalties is therefore granted.

B. *Additional testimony is necessary to determine the proper rate.*

In determining the appropriate ongoing royalty rate, the Court must consider: (1) change in bargaining position; (2) changed economic circumstances; and (3) any post-verdict factors affecting a post-verdict hypothetical negotiation. *See Vectura Ltd. v. GlaxoSmithKline LLC*, No. CV 16-638-RGA, 2019 WL 4346502, at *7 (D. Del. Sept. 12, 2019). "Generally, the jury's damages award is a starting point for evaluating ongoing royalties." *Apple, Inc.*, 2014 WL 6687122, at *14. Courts have increased the jury's royalty rate for ongoing infringement where "there was evidence of changed economic circumstances, in addition to the patentee being in a stronger bargaining position." *Purewick Corp. v. Sage Prod., LLC*, 666 F. Supp. 3d 419, 449 (D. Del. 2023), *appeal dismissed*, No. 2023-1868, 2023 WL 4230367 (Fed. Cir. June 28, 2023), *and appeal dismissed*, No. 2024-1184, 2024 WL 889332 (Fed. Cir. Mar. 1, 2024).

Here, given Jazz's status as the prevailing party, the Court agrees that Jazz is in a stronger bargaining position. *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1361 (Fed.Cir.2008) ("There is a

fundamental difference [] between a reasonable royalty for pre-verdict infringement and damages for post-verdict infringement.") (internal citations omitted).[14] Yet, the parties submitted limited briefing on any economic factors or post-verdict factors for the Court to consider in determining the appropriate ongoing rate. Also, given that Jazz was the only party to present testimony from a damages expert during trial, the Court finds that additional briefing and evidence is necessary to determine the extent to which Jazz's bargaining position and changes in the economic circumstances justify an increase in the rate awarded by the jury.[15] Accordingly, while the Court agrees that Jazz may be entitled to ongoing royalties at a rate greater than the 3.5% rate awarded by the jury, the Court will reserve judgment on the appropriate ongoing royalty rate to compensate Jazz for Avadel's future infringement in the narcolepsy market, pending additional briefing from the parties.

III. CONCLUSION

For the foregoing reasons, the Court **GRANTS-IN-PART** and **DENIES-IN-PART** Plaintiffs Jazz Pharmaceuticals Inc. and Jazz Pharmaceuticals Ireland Limited's Motion for a Permanent Injunction and for an Ongoing Royalty (D.I. 586). An appropriate Order will follow.

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[14]Indeed, "[p]rior to judgment, liability for infringement, as well as the validity of the patent, is uncertain, and damages are determined in the context of that uncertainty. Once a judgment of validity and infringement has been entered, however, the calculus is markedly different because different economic factors are involved." *Amado,* 517 F.3d at 1362. Accordingly, "[a]n assessment of prospective damages for ongoing infringement should 'take into account the change in the parties' bargaining positions, and the resulting change in economic circumstances, resulting from the determination of liability.'" *ActiveVideo*, 694 F.3d at 1343 (internal citations omitted).

[15]In deciding the royalty rate for post-trial infringement, the Court may consider "any new evidence that was not before the jury and additionally any changed circumstances (other than willfulness) between a hypothetical negotiation that occurred . . . (which the jury determined) and a hypothetical negotiation that would occur [now] after the judgment." *Mondis Tech. Ltd. v. Chimei InnoLux Corp.*, 822 F. Supp. 2d 639, 647 (E.D. Tex. 2011), *aff'd sub nom. Mondis Tech. Ltd. v. Innolux Corp.*, 530 Fed.Appx. 959 (Fed. Cir. 2013).

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendant.	C.A. No. 21-691-GBW
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendants.	C.A. No. 21-1138-GBW
JAZZ PHARMACEUTICALS, INC. and JAZZ PHARMACEUTICALS IRELAND LIMITED, Plaintiff, v. AVADEL CNS PHARMACEUTICALS LLC, Defendants.	C.A. No. 21-1594-GBW

ORDER

At Wilmington this 27th day of August 2024, **IT IS HEREBY ORDERED** that Plaintiffs Jazz Pharmaceuticals Inc. and Jazz Pharmaceuticals Ireland Limited's (collectively, "Jazz") Motion for a Permanent Injunction and for an Ongoing Royalty (D.I. 586) against Defendant Avadel CNS Pharmaceuticals LLC ("Avadel") is **GRANTED-IN-PART** and **DENIED-IN-PART** as follows:

1. Jazz's motion for a limited permanent injunction prohibiting Avadel from seeking approval from the U.S. Food and Drug Administration ("FDA") and marketing Lumryz for the treatment of IH is **GRANTED**, and Avadel and each of its officers, servants, employees, attorneys, and any other persons who are in active concert or participation with them, are hereby permanently enjoined from infringing in any way Claim 24 of the '782 patent, by making, using, or selling Lumryz or any product not more than colorably different from Lumryz, through and including the expiration date of the '782 patent, including any U.S. Patent Office extensions granted thereon.

    A. Excluded from this injunction are making, using, and selling Lumryz: (a) for the treatment of narcolepsy; (b) for the patients who have been prescribed Lumryz as of the effective date of the injunction conditional on Avadel paying appropriate renumeration to be determined; (c) in currently-ongoing clinical trials and studies; (d) to update data in old studies if necessary; and (e) to re-run necessary tests for quality control for regulators or customers.

B. For the avoidance of doubt, for the duration of this injunction, while Avadel may continue to use Lumryz in currently-ongoing clinical trials and studies pursuant to paragraph 1(A) above, Avadel may not seek approval of Lumryz from the FDA for the treatment of IH or for any indication that was not already part of Lumryz's approved product labeling as of March 4, 2024.

2. Jazz's motion for an ongoing royalty from Avadel to compensate Jazz for any future sale of infringing products to patients with narcolepsy is **GRANTED**, pending additional briefing on the appropriate ongoing rate above 3.5%. Each party may file an opening letter brief not to exceed seven (7) pages on or before Monday, September 16, 2024, at 5:00 pm, outlining their position on the appropriate ongoing royalty rate, which may include any evidence that was not before the jury and additionally any changed circumstances that support their respective positions. Each party may submit an answering letter brief not to exceed four (4) pages on or before Monday September 23, 2024, at 5:00 pm.

3. The undersigned expressly retains jurisdiction to enforce the judgment and permanent injunction pertaining to this action.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

EXHIBIT C

CONFIDENTIAL MATERIAL OMITTED

Transcript of Hearing on Plaintiff's Motion for a Permanent Injunction (June 6, 2024) (excerpts)

CONFIDENTIAL PURSUANT TO
PROTECTIVE ORDER (ECF Nos. 42, 75, 96)

EXHIBIT D

CONFIDENTIAL MATERIAL OMITTED

Avadel CNS Pharmaceuticals, LLC Letter (Aug. 29, 2024)

CONFIDENTIAL PURSUANT TO
PROTECTIVE ORDER (ECF Nos. 42, 75, 96)

EXHIBIT E

CONFIDENTIAL MATERIAL OMITTED

Jazz Pharmaceuticals, Inc. Letter (Aug. 30, 2024)

CONFIDENTIAL PURSUANT TO
PROTECTIVE ORDER (ECF Nos. 42, 75, 96)

EXHIBIT F

CONFIDENTIAL MATERIAL OMITTED

Defendant's Emergency Motion for Stay Pending Appeal (Sept. 3, 2024), ECF No. 670

CONFIDENTIAL PURSUANT TO
PROTECTIVE ORDER (ECF Nos. 42, 75, 96)

EXHIBIT G

CONFIDENTIAL MATERIAL OMITTED

Gudeman Declaration in Support of Defendant's Emergency Motion for Stay Pending Appeal (Sept. 3, 2024), ECF No. 672

CONFIDENTIAL PURSUANT TO
PROTECTIVE ORDER (ECF Nos. 42, 75, 96)

EXHIBIT H

CONFIDENTIAL MATERIAL OMITTED

Avadel CNS Pharmaceuticals, LLC Letter (Sept. 5, 2024)

CONFIDENTIAL PURSUANT TO
PROTECTIVE ORDER (ECF Nos. 42, 75, 96)

EXHIBIT I

CONFIDENTIAL MATERIAL OMITTED

Jazz Pharmaceuticals, Inc. Letter (Sept. 5, 2024)

CONFIDENTIAL PURSUANT TO
PROTECTIVE ORDER (ECF Nos. 42, 75, 96)

EXHIBIT J

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September 5, 2024

Frank C. Calvosa
Quinn Emanuel Urquhart & Sullivan LLP
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New York, NY 10010
frankcalvosa@quinnemanuel.com

Re: *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals, LLC*,
Fed. Cir. No. 24-2274

Dear Mr. Calvosa:

Thank you for your prompt response to yesterday's letter. Following up on item #5, Avadel confirms the following:

- Enrollment is ongoing and is anticipated to continue for approximately 12 months with a target of up to 150 participants enrolled and fewer than that actually finishing the trial.

- Enrollment numbers fluctuate day to day as new patients join the study and others leave the study.

- Some enrollees will be eligible for open label extensions as early as November 2024.

Regarding your questions on the number of current enrollees, Avadel's position is that (a) the current number of enrollees is not relevant, given that the overall targeted scope of the study is known and that, in Avadel's view, it is all protected activity under the safe harbor and part of an ongoing trial permitted by the Court's August 27th Order, and (b) Jazz has not articulated why it needs that information at this time. In light of this, we would appreciate your prompt response on #5.

With regard to item #6, please also confirm, as requested in my prior letter, that "Jazz agrees that the district court's injunction does not enjoin Avadel's application for FDA approval of Lumryz for pediatric patients with narcolepsy[.]" As a corollary, please confirm that Jazz has not and will not convey to the FDA that the district court's injunction order precludes FDA approval of Lumryz for pediatric patients with narcolepsy.

Finally, we now see no reason why the parties' negotiations and contentions regarding the interpretation of the Court's August 27th Order should be designated pursuant to the Protective Order. Accordingly, please confirm that your September 5th letter is not confidential under the Protective Order and may be shared within Avadel and publicly, as necessary. We confirm the same as to my September 4th letter.

Thank you for the productive dialogue.

Sincerely,

/s/ *Gabriel K. Bell*

Gabriel K. Bell
of LATHAM & WATKINS LLP

EXHIBIT K

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September 5, 2024

VIA EMAIL

HIGHLY CONFIDENTIAL

Gabriel K. Bell
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Re: *Jazz Pharmaceuticals, Inc. v. Avadel CNS Pharmaceuticals LLC,*
C.A. Nos. 21-691; 21-1138; 21-1594 (D. Del)

Dear Mr. Bell:

Thank you for your follow-up letter today. With respect to the IH issue, we remind Avadel that it is an adjudicated infringer of Jazz's valid patent, and that Avadel has been enjoined by the Court pursuant to the language of the Court's August 27, 2024 Order. Jazz has been trying to work with Avadel to find a compromise position, if possible, but Avadel's continued refusal to acknowledge this reality and lack of clarity regarding its activities with respect to IH has made the parties' communications unnecessarily difficult. In particular, with respect to item # 5, your letter is not responsive to our request given that Avadel refuses to state how many patients are currently enrolled in its IH clinical trial, how many patients in that study are on drug (as opposed to placebo), and how many patients will be participating in the open label extension portion of the study in the November 2024 to January 2025 time period. In your letter, you state that "Jazz has not articulated why it needs that information at this time." This is not the case and the statement is disappointing given our productive conversation yesterday. As we discussed, if Avadel were to provide the requested information, it would help Jazz to determine whether the parties could resolve Avadel's apparent refusal to comply with the Court's August 27, 2024 injunction Order. It is obvious that Avadel is attempting to get around the Court's injunction given Avadel's refusal to provide any specific information regarding its activities with respect to IH. We again reiterate our request that Avadel provide specific information responsive to Jazz's request.

With respect to item # 6, Jazz has agreed that it will not seek contempt proceedings with regard to the pediatric indication for narcolepsy. We do not understand the basis for your request regarding FDA communications. If the FDA has communicated with Avadel regarding the

injunction (or vice versa), please provide those communications to us so that Jazz can consider Avadel's request with full context.

Sincerely,

/s/ *Frank Calvosa*

Frank Calvosa

CERTIFICATE OF SERVICE

I hereby certify that on September 6, 2024, I caused the foregoing document to be electronically filed with the United States Court of Appeals for the Federal Circuit through the Court's CM/ECF system. All parties are represented by registered CM/ECF users and will be served by the CM/ECF system.

I further certify that I caused the confidential version of the foregoing document to be served via FedEx upon the following:

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I further certify that I caused the nonconfidential version of the foregoing document to be served via FedEx upon the following:

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/s/ Gabriel K. Bell
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